

CRYOLIFE INC  
Form 10-Q  
October 30, 2008

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended September 30, 2008

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Period from            to

Commission File Number 1-13165

**CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: CRYOLIFE INC - Form 10-Q

**Florida**  
(State or other jurisdiction of  
incorporation or organization)

**59-2417093**  
(I.R.S. Employer

Identification No.)

**1655 Roberts Boulevard, NW**

**Kennesaw, Georgia 30144**

(Address of principal executive offices)

(zip code)

**(770) 419-3355**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES  NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

The number of shares of common stock, par value \$0.01 per share, outstanding on October 27, 2008 was 28,134,639.

**Part I FINANCIAL INFORMATION****Item 1. Financial Statements.**

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Preservation services	\$ 14,188	\$ 11,347	\$ 41,337	\$ 36,019
Products	12,239	10,545	37,499	33,096
Other	377	268	691	580
<b>Total revenues</b>	<b>26,804</b>	<b>22,160</b>	<b>79,527</b>	<b>69,695</b>
<b>Costs and expenses:</b>				
Preservation services	7,615	6,575	22,382	21,183
Products	2,028	1,615	5,860	5,444
General, administrative, and marketing	12,072	11,240	36,497	34,417
Research and development	1,186	1,098	3,938	3,134
Interest expense	62	178	201	518
Interest income	(92)	(158)	(285)	(360)
Change in valuation of derivative				821
Other expense (income), net	142	(350)	115	(248)
<b>Total costs and expenses</b>	<b>23,013</b>	<b>20,198</b>	<b>68,708</b>	<b>64,909</b>
Income before income taxes	3,791	1,962	10,819	4,786
Income tax expense	235	55	610	234
<b>Net income</b>	<b>\$ 3,556</b>	<b>\$ 1,907</b>	<b>\$ 10,209</b>	<b>\$ 4,552</b>
Effect of preferred stock dividends				(243)
<b>Net income applicable to common shares</b>	<b>\$ 3,556</b>	<b>\$ 1,907</b>	<b>\$ 10,209</b>	<b>\$ 4,309</b>
<b>Income per common share:</b>				
Basic	\$ 0.13	\$ 0.07	\$ 0.37	\$ 0.17
Diluted	\$ 0.12	\$ 0.07	\$ 0.36	\$ 0.16
<b>Weighted average common shares outstanding:</b>				
Basic	27,899	27,501	27,741	25,998

Edgar Filing: CRYOLIFE INC - Form 10-Q

Diluted	28,703	28,056	28,384	26,673
---------	--------	--------	--------	--------

See accompanying Notes to Summary Consolidated Financial Statements.

## Item 1. Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES  
SUMMARY CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS)

	September 30, 2008	December 31, 2007
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 14,978	\$ 14,460
Marketable securities, at market		2,987
Restricted marketable securities	559	
Trade receivables, net	13,623	12,311
Other receivables	1,211	1,373
Deferred preservation costs, net	33,050	26,903
Inventories	7,058	5,607
Prepaid expenses and other current assets	2,389	1,811
<b>Total current assets</b>	<b>72,868</b>	<b>65,452</b>
Property and equipment, net	17,086	18,640
Patents, net	3,751	3,906
Trademarks and other intangibles, net	3,014	3,213
Deferred income taxes	148	148
Restricted money market funds	5,000	
Other long-term assets	1,149	1,325
<b>TOTAL ASSETS</b>	<b>\$ 103,016</b>	<b>\$ 92,684</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 3,485	\$ 2,956
Accrued compensation	2,878	2,963
Accrued procurement fees	5,073	5,161
Accrued expenses	5,540	5,611
Deferred income	1,599	1,111
Line of credit		4,506
Current maturities of notes payable and capital lease obligations	493	43
Other current liabilities	2,318	2,351
<b>Total current liabilities</b>	<b>21,386</b>	<b>24,702</b>
Line of credit	315	
Notes payable and capital lease obligations, less current maturities	71	81
Other long-term liabilities	4,774	5,274
<b>Total liabilities</b>	<b>26,546</b>	<b>30,057</b>

Edgar Filing: CRYOLIFE INC - Form 10-Q

Shareholders' Equity:		
Preferred stock		
Common stock (issued shares of 29,061 in 2008 and 28,526 in 2007)	291	285
Additional paid-in capital	124,527	120,562
Retained deficit	(42,772)	(52,981)
Accumulated other comprehensive loss	(22)	
Treasury stock at cost (shares of 955 in 2008 and 949 in 2007)	(5,554)	(5,239)
<b>Total shareholders' equity</b>	<b>76,470</b>	<b>62,627</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 103,016</b>	<b>\$ 92,684</b>

See accompanying Notes to Summary Consolidated Financial Statements.

**Item 1. Financial Statements.**

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Nine Months Ended September 30, 2008      2007 (Unaudited)	
Net cash from operating activities:		
Net income	\$ 10,209	\$ 4,552
Adjustments to reconcile net income to net cash from operating activities:		
Loss on sale or disposal of assets	17	127
Depreciation and amortization	3,284	3,349
Write-down of deferred preservation costs and inventory	1,390	667
Non-cash compensation	2,132	1,593
Change in valuation of derivative		821
Other non-cash adjustments	133	(284)
Changes in operating assets and liabilities:		
Receivables	(1,537)	(654)
Income taxes	194	(33)
Deferred preservation costs and inventories	(8,988)	(7,074)
Prepaid expenses and other assets	(732)	(89)
Accounts payable, accrued expenses, and other liabilities	567	1,913
Net cash provided by operating activities	6,669	4,888
Net cash from investing activities:		
Capital expenditures	(1,417)	(581)
Net proceeds from sale of assets	141	18
Restricted money market funds, long-term	(5,000)	
Purchases of marketable securities	(1,118)	(12,331)
Sales and maturities of marketable securities	3,565	11,155
Other	(93)	(164)
Net cash used in investing activities	(3,922)	(1,903)
Net cash from financing activities:		
Proceeds from issuance of debt and notes payable	428	408
Principal payments of debt	(4,582)	(414)
Proceeds from financing of insurance policies	1,300	1,912
Principal payments on capital leases and short-term notes payable	(897)	(1,274)
Proceeds from exercise of stock options and issuance of common stock	1,839	1,594
Payment of preferred stock dividends		(486)
Purchase of treasury stock	(315)	(478)
Net cash (used in) provided by financing activities	(2,227)	1,262
Increase in cash and cash equivalents	520	4,247
Effect of exchange rate changes on cash	(2)	(148)
Cash and cash equivalents, beginning of period	14,460	4,133

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cash and cash equivalents, end of period	\$ 14,978	\$ 8,232
--	-----------	----------

See accompanying Notes to Summary Consolidated Financial Statements.



---

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**Note 1 Basis of Presentation**

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc., and its subsidiaries (CryoLife, the Company, we, or us). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2007 has been derived from audited financial statements and the accompanying unaudited summary consolidated financial statements for the periods as of and ended September 30, 2008 and 2007 and have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (of normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

**Note 2 Exchange and Service Agreement**

On December 19, 2006 the Company announced that it had entered into an exchange and service agreement with Regeneration Technologies, Inc., (RTI) and certain of its affiliates, respecting procurement, processing, and distribution activities for cardiac and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife (the RTI Agreement). In accordance with the RTI Agreement, CryoLife ceased accepting donated human orthopaedic tissue for processing commencing January 1, 2007 and began work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiac and vascular tissues for processing and began work to transition its arrangements for recovery of these tissues to CryoLife. No cash was exchanged in the transaction. CryoLife continued to distribute its existing orthopaedic tissue inventory, and RTI continued to distribute its existing cardiac and vascular tissue inventory, through June 30, 2008. From July 1, 2008 through December 31, 2008 CryoLife is entitled to distribute RTI's remaining cardiac and vascular tissue inventory, and RTI is entitled to distribute CryoLife's remaining orthopaedic tissue inventory. CryoLife will pay RTI a commission with respect to any of CryoLife's orthopaedic tissue distributed by RTI and will receive a commission from RTI with respect to any RTI cardiac and vascular tissue distributed by CryoLife. Under the RTI Agreement, from July 1, 2008 through December 31, 2016, except as set forth above, CryoLife has agreed not to market or solicit orders for certain human orthopaedic tissues and RTI has agreed not to market or solicit orders for human cardiac and vascular tissues. The agreement also provides for a non-exclusive license of technology from CryoLife to RTI, and contains customary provisions regarding indemnification and confidentiality.

**Note 3 Cash Equivalents and Marketable Securities**

The Company maintains cash equivalents and marketable securities in accounts with several large, financial institutions, and the Company's policy excludes investment in any securities rated less than investment-grade by national rating services. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designations quarterly.

Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Trading securities are stated at their fair values, with the realized and unrealized gains and losses, interest, and dividends included in investment

Edgar Filing: CRYOLIFE INC - Form 10-Q

income. Debt securities not classified as held-to-maturity or marketable equity securities not classified as trading are classified as available-for-sale. Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of applicable income taxes, reported in a separate component of shareholders' equity. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in investment income. The cost of securities sold is based on the specific identification method.

As of September 30, 2008 \$5.0 million of the Company's money market funds were designated as long-term restricted money market funds due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation ( GE Capital ) as discussed in Note 6.

As of September 30, 2008 \$559,000 of marketable securities were designated as held-to-maturity due to a contractual commitment to hold the securities as pledged collateral relating to one of the Company's product liability insurance policies, and, therefore, they were reported as restricted marketable securities on the September 30, 2008 Summary Consolidated Balance Sheet.

As of December 31, 2007 \$3.0 million of marketable securities were designated as available-for-sale.

The Company's cash equivalents include advance funding received under the U.S. Congress 2005, 2006, and 2007 Defense Appropriations Conference Reports (the 2005 DOD Grant ), (the 2006 DOD Grant ), and (the 2007 DOD Grant ), respectively, for the continued development of protein hydrogel technology . The advance funding is accounted for as deferred income on the Summary Consolidated Balance Sheets and is recognized as other revenue as expenses are incurred related to these grants. As of September 30, 2008 \$1.6 million of cash equivalents and deferred income was related to the 2006 and 2007 DOD Grants. As of December 31, 2007 \$1.0 million of cash equivalents and deferred income was related to the 2005 and 2006 DOD Grants.

The following is a summary of cash equivalents and marketable securities (in thousands):

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
<b>September 30, 2008 (Unaudited)</b>			
Cash equivalents:			
Money market funds	\$ 12,848	\$	\$ 12,848
Restricted money market funds, long-term	\$ 5,000	\$	\$ 5,000
Marketable securities:			
Restricted government entity sponsored debt securities	\$ 559	\$	\$ 559
<b>December 31, 2007</b>			
Cash equivalents:			
Money market funds	\$ 11,724	\$	\$ 11,724
Marketable securities:			
Government entity sponsored debt securities	\$ 2,984	\$ 3	\$ 2,987

There were no gross realized gains or losses on sales of available-for-sale securities for the three and nine months ended September 30, 2008 and 2007. Differences between cost and market value listed above, consisting solely of an unrealized holding gain of \$3,000 at December 31, 2007, are included as a component of other comprehensive income on the Company's Summary Consolidated Balance Sheet.

At September 30, 2008 all of the Company's marketable securities had a maturity date between 90 days and one year. At December 31, 2007 all of the Company's marketable securities had a maturity date within 90 days.

**Note 4 Inventories**

Inventories are comprised of the following (in thousands):

	September 30, 2008	December 31, 2007
	(Unaudited)	
Raw materials	\$ 3,931	\$ 2,956
Work-in-process	493	650
Finished goods	2,634	2,001
Total inventories	\$ 7,058	\$ 5,607

**Note 5 Income Taxes**

The Company periodically assesses the recoverability of its deferred tax assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 109 Accounting for Income Taxes (SFAS 109), as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2007 the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, at December 31, 2007 and September 30, 2008 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized at this time. Therefore, as of September 30, 2008 and December 31, 2007 the Company had a total of \$28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$27,000. The Company will reverse the remaining valuation allowance, or a portion thereof, when and if its deferred tax assets meet the SFAS 109 more likely than not standard for recognition. Also, the realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers.

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, the Company recorded \$1.7 million in liabilities for unrecognized tax benefits plus estimated interest and penalties of \$283,000. The aggregate \$2.0 million liability was accounted for as a decrease to the January 1, 2007 balance of retained earnings of \$762,000 and a reclassification of a portion of the valuation allowances against the Company's deferred tax assets of \$1.2 million to an uncertain tax liability. To the extent these unrecognized tax benefits are ultimately recognized, it would not affect the annual effective income tax rate due to the existence of the valuation allowance.

The Company recognizes interest and penalties related to uncertain tax positions in other income and expense on the Company's Summary Consolidated Statements of Operations. As of September 30, 2008 and December 31, 2007 the Company had approximately \$411,000 and \$347,000, respectively, of accrued interest and penalties related to uncertain tax positions.

The tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**Note 6 Debt**

On March 26, 2008 CryoLife and its subsidiaries entered into a credit agreement with GE Capital as lender (the GE Credit Agreement). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$1.5 million). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. While the Company currently expects that its aggregate borrowing capacity under the GE Credit Agreement will equal \$15.0 million, there can be no assurance that the borrowing capacity will remain at this level.

The GE Credit Agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings before extraordinary gains, interest, taxes, depreciation, and amortization ( Adjusted EBITDA ) as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. Further, beginning April 15, 2008 as required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted money market funds on the Company's Summary Consolidated Balance Sheet, as they are restricted for the term of the GE Credit Agreement. The GE Credit Agreement also includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company's common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The GE Credit Agreement expires on March 25, 2011, at which time the outstanding principal balance will be due. As of September 30, 2008 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at either LIBOR plus 3.25% or GE Capital's base rate, as defined, plus 2.25%, as applicable. As of September 30, 2008 the outstanding balance of the GE Credit Agreement was \$315,000, the aggregate interest rate was 7.25%, and the remaining availability was \$14.7 million.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. ( Wells Fargo ) as lender which provided for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$2.0 million) or a borrowing base determined in accordance with the terms of the credit agreement. The credit agreement with Wells Fargo expired on February 8, 2008 in accordance with its terms, at which time the outstanding principal balance of \$4.5 million was paid from cash on hand. In the first quarter of 2007 the Company obtained a \$500,000 letter of credit under the subfacility of this credit agreement relating to one of the Company's product liability insurance policies. Upon the February 8, 2008 expiration of the credit agreement with Wells Fargo, the Company remitted to Wells Fargo approximately \$500,000 as collateral to cover the remaining term of the letter of credit agreement, which expired on April 2, 2008. This remitted amount was refunded to the Company in the second quarter of 2008.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In April 2008 the Company entered into such an agreement to finance approximately \$1.3 million in insurance premiums. The amount financed accrues interest at a 4.632% annual rate and is payable in equal monthly payments over a nine month period. As of September 30, 2008 the aggregate outstanding balance under this agreement was \$439,000. In the second quarter of 2007 the Company entered into two such agreements to finance approximately \$1.4 million and \$478,000 in insurance premiums. The amounts financed accrued interest at 7.027% and were payable in equal monthly payments over a nine month and an eight month period, respectively. As of September 30, 2008 and December 31, 2007 the aggregate outstanding balance under these agreements was zero.

#### **Note 7 Convertible Preferred Stock**

On March 18 and April 19, 2005 the Company completed a public offering of 417,000 shares of 6% convertible preferred stock (the Preferred Stock ) at a price to the public of \$50.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled approximately \$19.1 million.

Dividends on the Preferred Stock were cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly. Any dividends were required to be declared by the Company's Board of Directors and to come from funds legally available for dividend payments. On March 13, 2007 the Company declared a dividend of \$0.75 per share on its Preferred Stock. The dividend of approximately \$243,000 was paid on April 2, 2007 to shareholders of record on March 22, 2007. No dividends were declared during the remainder of 2007.

The Preferred Stock was convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 6.2189 shares of common stock for each share of Preferred Stock, based on an

initial conversion price of \$8.04. The Company had reserved 4.6 million shares of common stock for issuance upon conversion. Through June 4, 2007 holders had cumulatively voluntarily converted 139,000 shares of Preferred Stock into 867,000 shares of common stock.

The Preferred Stock contained provisions that allowed the Company to convert its Preferred Stock into common stock if the closing price of the Company's common stock exceeded \$12.06, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. This condition was satisfied on June 4, 2007 and on that day the Company exercised its right to automatically convert the Preferred Stock into common stock. As a result, on June 25, 2007 the Company automatically converted the remaining 278,000 shares of Preferred Stock into 1.7 million shares of common stock at the conversion rate of approximately 6.2189 shares of common stock per share of Preferred Stock.

The Company was required to make additional payments for both the voluntary and automatic conversions of Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock (the Dividend Make-Whole Payment). The Dividend Make-Whole Payment was payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. The Dividend Make-Whole Payment is discussed further in Note 8 below.

As of September 30, 2008 and December 31, 2007 there were no outstanding shares of Preferred Stock as a result of the second quarter 2007 automatic conversion of the Preferred Stock to common stock.

#### **Note 8 Derivative**

In accordance with SFAS No. 133 Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the Company was required to separate and account for the Dividend Make-Whole Payment feature of its Preferred Stock as an embedded derivative (the Derivative). As an embedded derivative instrument, the Dividend Make-Whole Payment feature was measured at fair value and reflected as a current liability on the Company's Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative were recognized in the line item change in valuation of derivative on the Company's Summary Consolidated Statements of Operations.

The Company determined the fair value of the Derivative to be \$1.0 million on March 18, 2005, the date of issuance. The Company determined the fair value of the Derivative related to the issuance of additional Preferred Stock upon exercise of the underwriter's over allotment option to be \$32,000 on April 19, 2005, the date of issuance. The proceeds from the Preferred Stock recorded on the Summary Consolidated Balance Sheets were reduced by these amounts, which were allocated to the derivative liability.

As discussed in Note 7 above, on June 25, 2007 the Company automatically converted the remaining shares of the Preferred Stock into common stock, thereby, triggering the payment of the remaining Dividend Make-Whole Payment. Through June 4, 2007 the Company had issued 132,000 shares of common stock to converting holders in satisfaction of the Dividend Make-Whole Payment. The value of voluntary conversions during 2007 was \$178,000 based on the share prices on the respective dates of conversion. On June 25, 2007 the Company issued 69,000 shares of common stock to preferred shareholders to satisfy the Dividend Make-Whole Payment due to the automatic conversion. The value of the Dividend Make-Whole Payment was \$878,000 based on the share price of \$12.71 on the date of conversion.

The Company recorded \$821,000 for the nine months ended September 30, 2007 related to the first quarter revaluation of the Derivative and the automatic and voluntary conversion of the Preferred Stock to common stock.

At September 30, 2008 and December 31, 2007 there was no remaining derivative liability as a result of the second quarter 2007 automatic conversion of the Preferred Stock to common stock.

**Note 9 Comprehensive Income**

The following is a summary of comprehensive income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
Net income	\$ 3,556	\$ 1,907	\$ 10,209	\$ 4,552
Unrealized gain (loss) on investments		11	(3)	7
Translation adjustment	(31)	(93)	(19)	(151)
Comprehensive income	\$ 3,525	\$ 1,825	\$ 10,187	\$ 4,408

The tax effect on the change in unrealized gain (loss) on investments and the translation adjustment is zero for each period presented.

Accumulated other comprehensive loss consists of the following (in thousands):

	September 30 2008	December 31, 2007
	(Unaudited)	
Unrealized gain on investments	\$	\$ 3
Translation adjustment	(22)	(3)
Total accumulated other comprehensive loss	\$ (22)	\$

**Note 10 Income per Common Share**

The following table sets forth the computation of basic and diluted income per common share (in thousands, except per share data). The net income for the nine months ended September 30, 2007 is adjusted by the effect of the Company's cumulative, convertible Preferred Stock to arrive at net income applicable to common shares in accordance with SFAS No. 128 Earnings Per Share ( SFAS 128 ). The Company also considers, as applicable, the effect of its Preferred Stock, as discussed in Note 7, the Derivative, as discussed in Note 8, common stock options, as discussed in Note 11, contingently returnable shares, and contingent stock awards in the calculation of diluted weighted-average shares below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
Basic income per common share				
Numerator:				
Net income	\$ 3,556	\$ 1,907	\$ 10,209	\$ 4,552
Effect of preferred stock <sup>a</sup>				(243)
Net income applicable to common shares	\$ 3,556	\$ 1,907	\$ 10,209	\$ 4,309

Edgar Filing: CRYOLIFE INC - Form 10-Q

Denominator:

Basic weighted-average common shares	27,899	27,501	27,741	25,998
--------------------------------------	--------	--------	--------	--------

Basic income per common share	\$ 0.13	\$ 0.07	\$ 0.37	\$ 0.17
-------------------------------	---------	---------	---------	---------

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
Diluted income per common share				
Numerator:				
Net income	\$ 3,556	\$ 1,907	\$ 10,209	\$ 4,552
Effect of preferred stock <sup>a, b</sup>				(243)
Net income applicable to common shares	\$ 3,556	\$ 1,907	\$ 10,209	\$ 4,309
Denominator:				
Basic weighted-average common shares	27,899	27,501	27,741	25,998
Effect of dilutive convertible preferred stock <sup>b</sup>				
Effect of dilutive stock options	697	555	557	675
Effect of contingently returnable shares <sup>c</sup>	73		56	
Effect of contingent stock awards <sup>d</sup>	34		30	
Adjusted weighted-average common shares	28,703	28,056	28,384	26,673
Diluted income per common share	\$ 0.12	\$ 0.07	\$ 0.36	\$ 0.16

<sup>a</sup> The amount of the accumulated dividend on Preferred Stock reduced the net income applicable to common shares for the nine months ended September 30, 2007.

<sup>b</sup> The amount of the accumulated dividend on the Preferred Stock decreased the net income applicable to common shares by \$243,000 for the nine months ended September 30, 2007. The adjustment for the Dividend Make-Whole Payment for conversions during the period and the adjustment for the quarterly revaluation of the derivative liability would have instead increased net income applicable to common shareholders by \$821,000 for the nine months ended September 30, 2007. The common shares that would have been issued to shareholders at the beginning of the period for the conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 1.3 million for the nine months ended September 30, 2007. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

<sup>c</sup> Contingently returnable shares include shares of common stock issued pursuant to stock grants which have not vested and are returnable to the Company upon forfeiture.

<sup>d</sup> Contingent stock awards include shares to be issued pursuant to performance based bonus plans that have been approved by the compensation committee of the Board of Directors.

In future periods basic and diluted earnings per common share are expected to be affected by the fluctuations in the fair value of the Company's common stock, the exercise and issuance of additional stock options, contingently returnable shares, and contingent stock awards.

#### Note 11 Stock Compensation

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of shares and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each three-month offering period. Pursuant to the adoption of SFAS 123 Revised Share-Based Payment (SFAS 123R), both the Company's 15% discount on ESPP stock purchases and the look back portion of ESPP stock purchases are considered components of stock compensation and



must be expensed in the Company's

financial statements. The look back portion of the Company's ESPP constitutes an option and, as such, the expense is determined by performing a valuation as discussed below.

### ***Stock Grants***

The Company values its stock grants based on the market value, as determined by the applicable stock incentive plan, on the date of grant. The value of stock grants is expensed over the vesting period of the related grant, and an estimated forfeiture rate is used to reduce the expense recorded.

In February 2008 the Compensation Committee of the Company's Board of Directors approved the terms of the Company's 2008 performance-based bonus plans to recognize the performance of the Company's executives and managers. A portion of the awards to be issued under these plans will be paid in Company stock pursuant to the Company's existing stock incentive plans, if the required performance is achieved. The Company recorded an accrual of \$695,000 related to this contingent stock grant during the nine months ended September 30, 2008. The Company expects to pay out cash and stock related to these bonus plans in the first quarter of 2009.

During the nine months ended September 30, 2008 the Compensation Committee of the Company's Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives and managers totaling 183,000 shares of common stock, which had an aggregate value of \$1.8 million. The grants of stock during the nine months ended September 30, 2008 include 81,000 shares of common stock valued at \$786,000 issued as part of the 2007 performance-based bonus plans for certain Company executives and managers. The Company recorded the expense related to the 2007 performance-based bonus plans during the year ended December 31, 2007. The remaining value of the stock granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

During the nine months ended September 30, 2007 the Compensation Committee of the Company's Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives totaling 156,000 shares of common stock, which had an aggregate value of \$1.5 million. The grants of stock during the nine months ended September 30, 2007 included 68,000 shares of common stock valued at \$587,000 issued as part of the 2006 performance-based bonus plan for certain Company executives. The Company recorded the expense related to the 2006 performance-based bonus plan during the year ended December 31, 2006. The remaining value of the stock granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

### ***Stock Options***

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company executives and employees totaling 403,000 and 383,000 shares during the nine months ended September 30, 2008 and 2007, respectively, with exercise prices equal to the stock prices on the respective grant dates. The value of the stock options granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

Employees purchased common stock totaling 38,000 and 36,000 shares in the nine months ended September 30, 2008 and 2007, respectively, through the Company's ESPP. The value of the discount and the option portion of the stock purchased was recorded as an expense on the Company's Summary Consolidated Statements of Operations in each quarterly period in accordance with SFAS 123R as discussed below.

### ***Stock Compensation Expense***

The Company uses the Black-Scholes model to value its stock option grants under SFAS 123R and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company's ESPP options is also determined using the Black-Scholes model and is expensed quarterly at the end of the purchase period, as the option is fully vested at that time. The fair value of stock options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate. The

Edgar Filing: CRYOLIFE INC - Form 10-Q

term assumption is primarily based on the contractual term of the option and historic data related to exercise and post-vesting cancellation history experienced by the Company, adjusted based on management's expectations of future results. The expected term is determined separately for options issued to the Company's directors and to employees. The Company's anticipated volatility level is primarily based on the historic volatility of the Company's common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management's expectations of future volatility, for the life of the option or option group. The Company's model includes a zero dividend yield assumption, as the Company has not historically paid nor does it anticipate paying dividends on its common stock. The risk free interest rate is based on recent U.S. Treasury note auction results with a similar life to that of the option. The Company's model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions. The period expense is then determined based on the valuation of the options, and at that time an estimated forfeiture rate is used to reduce the expense recorded. The Company's estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company, and the expense recorded is adjusted to reflect actual forfeitures at each vesting date.

The following weighted-average assumptions were used to determine the fair value of options under SFAS 123R:

	Three Months Ended		Nine Months Ended	
	September 30, 2008		September 30, 2008	
	Stock Options	ESPP Options	Stock Options	ESPP Options
	(Unaudited)		(Unaudited)	
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.60	.57	.60	.61
Risk-free interest rate	2.72%	1.87%	2.34%	2.25%
Expected life of options	3.5 Years	.25 Years	3.5 Years	.25 Years

  

	Three Months Ended		Nine Months Ended	
	September 30, 2007		September 30, 2007	
	Stock Options	ESPP Options	Stock Options	ESPP Options
	(Unaudited)		(Unaudited)	
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.60	.63	.60	.49
Risk-free interest rate	4.25%	4.55%	4.62%	4.85%
Expected life of options	3.3 Years	.25 Years	3.4 Years	.25 Years

The following table summarizes stock compensation expenses (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
Stock grant expense	\$ 438	\$ 386	\$ 1,277	\$ 961
Stock option expense	260	240	855	632
<b>Total stock compensation expense</b>	<b>\$ 698</b>	<b>\$ 626</b>	<b>\$ 2,132</b>	<b>\$ 1,593</b>

Included in this total stock compensation expense were expenses related to common stock grants, options issued prior and subsequent to the adoption of SFAS 123R that continue to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as compensation expense and were subject to the Company's normal allocation of expenses to inventory and deferred preservation costs. The Company capitalized \$39,000 and \$25,000 in the three months ended September 30, 2008 and 2007, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs. The Company capitalized \$88,000 and \$69,000 in the nine months ended

## Edgar Filing: CRYOLIFE INC - Form 10-Q

September 30, 2008 and 2007, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs. The Company did not recognize a tax benefit related to the compensation expense recorded in the three and nine months ended September 30, 2008 and 2007, as the Company is maintaining a full valuation allowance on its deferred tax assets. See Note 5 for additional discussions of the Company's income tax valuation.

As of September 30, 2008 and 2007 the Company had a total of \$1.1 million and \$699,000, respectively, in total unrecognized compensation costs related to unvested stock grants, before considering the effect of expected forfeitures. This expense is expected to be recognized over each stock grant's vesting period. As of September 30, 2008 the Company has outstanding stock grants that complete vesting in 2008, 2010, and 2011.

As of September 30, 2008 and 2007 there was approximately \$3.6 million and \$3.0 million, respectively, in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2008 this expense is expected to be recognized over a weighted average period of 1.5 years.

**Note 12 Segment Information**

The Company has two reportable segments organized according to its services and products: Preservation Services and Medical Devices.

The Preservation Services segment includes external services revenues from the cryopreservation of cardiac and vascular tissues and from shipments of previously cryopreserved orthopaedic tissues. The Medical Devices segment includes external revenues from product sales of BioGlue<sup>®</sup>, Hemostase MPH<sup>®</sup>, CardioWrap<sup>®</sup>, and bioprosthetic devices, including the CryoLife-O Brieß<sup>®</sup> Stentless Aortic Bioprosthesis. The Medical Devices segment also includes SynerGraft<sup>®</sup> processed bovine vascular grafts for the three and nine months ended September 30, 2007. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of preservation services and products. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of preservation services and products, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Preservation services	\$ 14,188	\$ 11,347	\$ 41,337	\$ 36,019
Medical devices	12,239	10,545	37,499	33,096
All other <sup>a</sup>	377	268	691	580
	26,804	22,160	79,527	69,695
<b>Cost of Preservation Services and Products:</b>				
Preservation services	7,615	6,575	22,382	21,183
Medical devices	2,028	1,615	5,860	5,444
All other <sup>a</sup>				
	9,643	8,190	28,242	26,627
<b>Gross Margin:</b>				
Preservation services	6,573	4,772	18,955	14,836
Medical devices	10,211	8,930	31,639	27,652
All other <sup>a</sup>	377	268	691	580
	\$ 17,161	\$ 13,970	\$ 51,285	\$ 43,068

Edgar Filing: CRYOLIFE INC - Form 10-Q

<sup>a</sup> The All other designation includes 1) grant revenues in all periods presented and 2) revenues related to the licensing of the Company's technology to a third party in the three months ended September 30, 2007 and nine months ended September 30, 2008 and 2007.

The following table summarizes net revenues by service or product (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
<b>Preservation services:</b>				
Cardiac tissue	\$ 7,034	\$ 5,566	\$ 19,620	\$ 15,587
Vascular tissue	7,116	5,215	21,055	16,782
Orthopaedic tissue	38	566	662	3,650
<b>Total preservation services</b>	<b>14,188</b>	<b>11,347</b>	<b>41,337</b>	<b>36,019</b>
<b>Products:</b>				
BioGlue	11,623	10,280	36,482	32,373
Other medical devices	616	265	1,017	723
<b>Total products</b>	<b>12,239</b>	<b>10,545</b>	<b>37,499</b>	<b>33,096</b>
Other	377	268	691	580
<b>Total revenues</b>	<b>\$ 26,804</b>	<b>\$ 22,160</b>	<b>\$ 79,527</b>	<b>\$ 69,695</b>

### Note 13 Commitments and Contingencies

#### *Product Liability Claims*

In the normal course of business as a medical device and services company, the Company has liability and tissue processing complaints filed against it. As of October 27, 2008 one liability lawsuit was pending against the Company arising out of the Company's allograft orthopaedic tissue preservation services. Management believes this lawsuit is covered by liability insurance. This lawsuit is in the discovery stage. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of September 30, 2008, the Company accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses on the September 30, 2008 Summary Consolidated Balance Sheet. As of December 31, 2007 the Company had accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses on the December 31, 2007 Summary Consolidated Balance Sheet.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product and tissue processing liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of June 30, 2008 and December 31, 2008. The independent firm estimated the unreported loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's

historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims



model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported loss liability including:

A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,

The future claim reporting lag time would be a blend of the Company's experiences and industry data,

The frequency of unreported claims for accident years 2001 through 2008 would be lower than the Company's experience in the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,

The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,

The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and

The number of BioGlue claims per million dollars of BioGlue revenue would be 55% lower than non-BioGlue claims per million dollars of revenue. The 55% factor was selected based on BioGlue claims experience to date and consultation with the actuary.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported liability loss, but the accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

Based on the actuarial valuation performed in July 2008 as of June 30, 2008 and December 31, 2008, the Company estimated that its liability for unreported product liability claims was \$4.9 million as of June 30, 2008 and would be \$5.4 million as of December 31, 2008. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued at September 30, 2008 a prorated amount of \$5.2 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2008. The \$5.2 million balance is included as a component of accrued expenses of \$2.6 million and other long-term liabilities of \$2.6 million on the September 30, 2008 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$10.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2008, \$1.7 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.7 million insurance recoverable is included as a component of other receivables of \$900,000 and other long-term assets of \$800,000 on the September 30, 2008 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to September 30, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued \$6.3 million for unreported liability claims and recorded a receivable of \$2.4 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.3 million accrual was included as a component of accrued expenses of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Summary Consolidated Balance Sheet. The \$2.4 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Summary Consolidated Balance Sheet.

#### **Note 14 New Accounting Pronouncements**

The Company was required to adopt SFAS No. 157 Fair Value Measurements ( SFAS 157 ) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The adoption of SFAS 157 did not have a material effect on the Company's results of operations or financial position.

The Company was required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. The adoption of SFAS 159 did not have a material effect on the Company s results of operations or financial position.

The Company will be required to adopt SFAS No. 141R Business Combinations ( SFAS 141R ) for the fiscal year beginning January 1, 2009. FAS 141R establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The Company does not expect the adoption of FAS 141R to have a material effect on its consolidated financial position, results of operations, or cash flows.

---

## PART I - FINANCIAL INFORMATION

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### Overview

CryoLife, Inc. (CryoLife, the Company, we, or us) develops and commercializes biomaterials and medical devices, and preserves and distributes human tissues for cardiac and vascular transplant applications. The Company's human tissues include the CryoValve<sup>®</sup> SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft<sup>®</sup> Technology. The Company's biomaterials and medical devices include BioGlue<sup>®</sup> Surgical Adhesive (BioGlue), CryoLife-O<sup>®</sup> Bristentless Porcine Aortic Bioprosthesis, and ProPatch<sup>®</sup> Soft Tissue Repair Matrix (ProPatch). Additionally, the Company distributes a microporous polysaccharide hemostatic agent (coagulant) under the private label Hemostase MPH<sup>®</sup> for Medafor, Inc. (Medafor) and CardioWrap<sup>®</sup> bioresorbable thin film sheet used in cardiac reconstruction for MAST BioSurgery, Inc. (MAST).

In the quarter ended September 30, 2008 CryoLife revenues were \$26.8 million, including preservation services revenues of \$14.2 million and BioGlue revenues of \$11.6 million. Preservation services revenues remained strong, led by double digit quarter-over-quarter growth in cardiac preservation service revenues. Cardiac revenues continue to be favorably impacted by shipments of the Company's CryoValve SG pulmonary human heart valve (CryoValve SG) following its reintroduction in March of this year. Also during the third quarter CryoLife continued with its launch of Hemostase MPH in the US, the UK, and Germany, and announced the expansion of its distribution into France and Canada.

See Results of Operations below for further discussion of the Company's financial results during the quarter ended September 30, 2008.

#### Critical Accounting Policies

A summary of the Company's significant accounting policies is included in Part II, Item 8, Note 1 of the Notes to Consolidated Financial Statements, contained in the Company's Form 10-K for the fiscal year ended December 31, 2007. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information, which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company's financial condition and results and may involve a higher degree of judgment and complexity.

**Product Liability Claims:** In the normal course of business as a medical device and services company, the Company has liability and tissue processing complaints filed against it. As of October 27, 2008 one liability lawsuit was pending against the Company arising out of the Company's allograft orthopaedic tissue preservation services. Management believes this lawsuit is covered by liability insurance. This lawsuit is in the discovery stage. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of September 30, 2008, the Company accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses on the September 30, 2008 Summary Consolidated Balance Sheet. As of December 31, 2007 the Company had accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses on the December 31, 2007 Summary Consolidated Balance Sheet.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior

to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product and tissue processing liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of June 30, 2008 and December 31, 2008. The independent firm estimated the unreported loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported loss liability including:

- A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,
- The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- The frequency of unreported claims for accident years 2001 through 2008 would be lower than the Company's experience in the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,
- The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,
- The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- The number of BioGlue claims per million dollars of BioGlue revenue would be 55% lower than non-BioGlue claims per million dollars of revenue. The 55% factor was selected based on BioGlue claims experience to date and consultation with the actuary.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported liability loss, but the accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

Based on the actuarial valuation performed in July 2008 as of June 30, 2008 and December 31, 2008, the Company estimated that its liability for unreported product liability claims was \$4.9 million as of June 30, 2008 and would be \$5.4 million as of December 31, 2008. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued at September 30, 2008 a prorated amount of \$5.2 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2008. The \$5.2 million balance is included as a component of accrued expenses of \$2.6 million and other long-term liabilities of \$2.6 million on the September 30, 2008 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$10.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2008, \$1.7 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.7 million insurance recoverable is included as a component of other receivables of \$900,000 and other long-term assets of \$800,000 on the September 30, 2008 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to September 30, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued \$6.3 million for unreported liability claims and recorded a receivable of \$2.4 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.3 million accrual was included as a component of accrued expenses of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Summary Consolidated Balance Sheet. The \$2.4 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Summary Consolidated Balance Sheet.

**Deferred Preservation Costs:** By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and further processes cannot be held as inventory. Tissue is procured from deceased human donors by organ and tissue procurement agencies, which consign the tissue to the Company for processing, preservation, and distribution. Preservation costs consist primarily of direct labor and materials (including salary and fringe benefits, laboratory expenses, tissue procurement fees, and freight-in charges) and indirect costs (including allocations of costs from departments that support processing activities and facility allocations). Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for in accordance with ARB No. 43 Chapter 4 Inventory Pricing ( ARB 43 ). Preservation costs are stated at the lower of cost or market on a first-in, first-out basis and are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Cost of preservation services also includes idle facility expense, excessive spoilage, double freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 151 Inventory Costs ( SFAS 151 ).

The calculation of deferred preservation costs involves a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company's contracts with independent procurement agencies, and freight-in charges, which are estimated based on the Company's prior experiences with these charges. These costs are adjusted for differences between estimated and actual fees when invoices for these services are received. Management believes that its estimates approximate the actual costs of these services, but estimates could differ from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the number of tissues processed. At each balance sheet date a portion of the deferred preservation costs relates to tissues currently in active processing or held in quarantine pending release to implantable status. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could materially impact the amount of deferred preservation costs on the Company's Summary Consolidated Balance Sheets and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company's Summary Consolidated Statements of Operations.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value and to determine if there are any impairments to the book value of the Company's deferred preservation costs. CryoLife records a charge to cost of preservation services to write-down the amount of deferred preservation costs that are not deemed to be recoverable. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels when tissues are shipped or become available for shipment.

The Company recorded a write-down of \$348,000 for the nine months ended September 30, 2007 for the value of certain deferred preservation costs that exceeded market value. The write-down was primarily due to excess tissue processing costs incurred in that period that exceeded market value based on then recent average service fees. Actual results may differ from these estimates.

The Company recorded write-downs of \$172,000 for the nine months ended September 30, 2008 due to the impairment of certain vascular tissues. The Company recorded write-downs of \$208,000 and \$319,000 for the three and nine months ended September 30, 2007, respectively, due to the impairment of certain vascular and orthopaedic

tissues. The tissues were impaired in the period that the Company determined that the tissues were not expected to ship prior to the expiration date of the tissue's packaging.

As of September 30, 2008 deferred preservation costs consisted of \$11.1 million for allograft heart valve tissues, \$1.9 million for non-valved cardiac tissues, \$20.0 million for vascular tissues and zero for orthopaedic tissues. As of December 31, 2007 deferred preservation costs consisted of \$7.6 million for allograft heart valve tissues, \$2.1 million for non-valved cardiac tissues, \$17.1 million for vascular tissues, and \$123,000 for orthopaedic tissues.

**Deferred Income Taxes:** Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses.

The Company periodically assesses the recoverability of its deferred tax assets in accordance with SFAS No. 109 Accounting for Income Taxes ( SFAS 109 ), as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against the deferred tax asset when, as a result of this analysis, management believes it is more likely than not that some portion or all of its deferred tax assets will not be realized.

As of December 31, 2007, the Company determined that its deferred tax assets required a valuation allowance of \$28.2 million. This analysis included consideration of a variety of factors in accordance with SFAS 109, which included the Company's historical operating results and uncertainties regarding projected future operating results.

Based on the Company's projections for the full year of 2008, the Company anticipates that it will utilize a portion of its net operating loss carryforwards in its 2008 income tax year to offset its U.S. taxable income, as it did in the 2007 and 2006 tax years. However, the Company currently believes that a change in its determination of the recoverability of the related deferred tax asset is not yet warranted because, in accordance with the guidance in SFAS 109, as explained further below, the Company's historical net losses constitute significant evidence against the recoverability of its deferred tax assets that is difficult to overcome. Therefore, as of September 30, 2008 the Company determined that it was necessary to maintain the valuation allowance on its deferred tax assets. As of September 30, 2008 the Company had a total of \$28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$27,000.

The Company reassesses the recoverability of its deferred tax assets and the appropriate levels of the valuation allowance on a quarterly basis. In conducting this assessment, management considers a variety of factors, including Company estimates of taxable income for future years, as well as the reasons for the Company's operating losses in prior years, its recent improvements to profitability, and management's judgment as to the likelihood of continued profitability and expectations of future performance, and other factors. Under SFAS No. 109, concluding that a valuation allowance is not required is difficult when there is significant negative evidence which is objective and verifiable, such as cumulative losses in recent years.

Due to the nature of the analysis required under SFAS No. 109, if the Company's operations continue to be profitable, it is likely that all or a portion of the valuation allowance will be reversed. At the time of reversal, the Company will record a corresponding non-cash gain that is likely to have a material impact on the Company's results of operations during the period in which the reversal occurs. In periods following the reversal, the Company's effective income tax rate will be significantly higher than the effective income tax rate experienced in periods prior to the reversal.

The realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers. The tax years 2004 to 2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

---

**Impairments of Long-Lived Assets:** The Company assesses the potential impairment of its long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include the following:

- Significant underperformance relative to expected historical or projected future operating results,
- Significant negative industry or economic trends,
- Significant decline in the Company's stock price for a sustained period, or
- Significant decline in the Company's market capitalization relative to net book value.

SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets ( SFAS 144 ), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. For the year ended December 31, 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted.

SFAS No. 142 Goodwill and Other Intangible Assets ( SFAS 142 ) requires that goodwill resulting from business acquisitions and other non-amortizing intangible assets be subject to annual impairment testing. The Company's non-amortizing intangible assets as of December 31, 2007 consist of trademarks and, as a result of the Company's agreement with Regeneration Technologies, Inc. ( RTI ) and certain of its affiliates as discussed in Item 1, Note 2 of the Notes to Summary Consolidated Financial Statements, procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI. In accordance with SFAS 142, the Company performed an analysis on its non-amortizing intangible assets as of December 31, 2007. Based on the results of its analysis, the Company did not believe that an impairment existed related to its non-amortizing intangible assets as of December 31, 2007. Management will continue to evaluate the recoverability of these non-amortizing intangible assets at least on an annual basis in accordance with SFAS 142.

For the nine months ended September 30, 2008 the Company did not experience any changes that would materially affect the Company's analysis of and recoverability of any of its long-lived assets.

#### **New Accounting Pronouncements**

The Company was required to adopt SFAS No. 157 Fair Value Measurements ( SFAS 157 ) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The adoption of SFAS 157 did not have a material effect on the Company's results of operations or financial position.

The Company was required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. The adoption of SFAS 159 did not have a material effect on the Company's results of operations or financial position.

The Company will be required to adopt SFAS No. 141R Business Combinations ( SFAS 141R ) for the fiscal year beginning January 1, 2009. FAS 141R establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The Company does not expect the adoption of FAS 141R to have a material effect on its consolidated financial position, results of operations, or cash flows.

**Results of Operations**

(Tables in thousands)

**Revenues**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Total Revenues	\$ 26,804	\$ 22,160	\$ 79,527	\$ 69,695

Revenues increased 21% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. Revenues increased 14% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007.

The increase in the three and nine months ended September 30, 2008 was primarily due to an increase in tissue preservation services revenues and BioGlue revenues, as compared to the prior year periods.

A detailed discussion of the change in preservation services revenues for each of the major tissue types distributed by the Company and the change in BioGlue and other medical device revenues is presented below.

**Cardiac Preservation Services**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 7,034	\$ 5,566	\$ 19,620	\$ 15,587
Cardiac revenues as a percentage of total revenues	26%	25%	25%	22%

Revenues from cardiac preservation services increased 26% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. This increase was primarily due to the aggregate impact of favorable tissue mix and a 3% increase in unit shipments of cardiac tissues, which together increased revenues by 21%, and an increase in average service fees, which increased revenues by 5%.

Revenues from cardiac preservation services increased 26% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. This increase was primarily due to the aggregate impact of favorable tissue mix and an 11% increase in unit shipments of cardiac tissues, which together increased revenues by 17%, and an increase in average service fees, which increased revenues by 9%.

The favorable tissue mix and volume increase for the three and nine months ended September 30, 2008 was primarily due to the favorable impact of the CryoValve SG pulmonary human heart valve ( CryoValve SG ), both due to the fact that shipments of CryoValve SG command a premium fee over standard processed pulmonary valves (favorable tissue mix) and due to the net increase in valve shipments when taking into effect shipments of the CryoValve SG and the related reduction in shipments of standard processed pulmonary valves.

The favorable tissue mix from CryoValve SG was due to the February 7, 2008 FDA clearance of the Company's 510(k) premarket notification for the CryoValve SG and its subsequent reintroduction in March 2008 coupled with the premium fee charged for the CryoValve SG over the standard processed CryoValve. For the three and nine months ended September 30, 2008, CryoValve SG revenues accounted for 25% and 17%, respectively, of the Company's total cardiac preservation service revenues. The increase in average service fees for the three and nine months ended September 30, 2008 was primarily due to the fee increases that went into effect in January 2008 on most standard processed cardiac tissues.



Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, decreased 8% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. The Company's procurement of cardiac tissues increased 6% for the nine months ended

September 30, 2008 as compared to the nine months ended September 30, 2007. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include but are not limited to, the likelihood that certain tissues will pass the Company's quality controls and testing processes, changes in demand for certain types of tissues processed by the Company, changes in incoming tissue availability, and the level of tissues currently available for shipment. The decrease in cardiac procurement in the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 was primarily the result of changes in tissue acceptance criteria made during the current year quarter. If these changes remain in effect, the Company believes that cardiac procurement will continue at these reduced levels through 2008 as compared to the prior year periods. However, the Company may continue to make changes in incoming tissue acceptance criteria, and as a result the Company's level of procurement may continue to vary from quarter-to-quarter and year-to-year. The Company believes that its existing cardiac tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for cardiac tissues for the reasonably foreseeable future.

The Company has experienced and could continue to experience an increase in its 2008 cardiac preservation services revenues as compared to 2007 as a result of continued shipments of the CryoValve SG, which have a premium fee over the standard processed CryoValve. However, there can be no assurance that the CryoValve SG will continue to command premium fees or that shipments of the CryoValve SG will continue to occur at material levels.

***Vascular Preservation Services***

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 7,116	\$ 5,215	\$ 21,055	\$ 16,782
Vascular revenues as a percentage of total revenues	27%	24%	26%	24%

Revenues from vascular preservation services increased 36% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. This increase was primarily due to a 34% increase in unit shipments of vascular tissues, which increased revenues by 32%, and an increase in average service fees, which increased revenues by 4%.

Revenues from vascular preservation services increased 25% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. This increase was primarily due to a 22% increase in unit shipments of vascular tissues, which increased revenues by 20%, and an increase in average service fees, which increased revenues by 5%.

The increase in vascular volume for the three and nine months ended September 30, 2008 was primarily due to increases in shipments of saphenous veins, due to the strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations. The increase in average service fees for the three and nine months ended September 30, 2008 was primarily due to the fee increases that went into effect in January 2008 on most vascular tissues.

The Company's procurement of vascular tissues decreased 8% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. The Company's procurement of vascular tissues decreased 5% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include but are not limited to, the likelihood that certain tissues will pass the Company's quality controls and testing processes, changes in demand for certain types of tissues processed by the Company, changes in incoming tissue availability, and the level of tissues currently available for shipment. The decrease in vascular procurement in the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007, respectively, was primarily the result of changes in tissue acceptance criteria made during the current year. If these changes remain in effect, the Company believes that vascular procurement will continue at these reduced levels through 2008 as compared to the prior year periods.

However, the Company may continue to make changes in incoming tissue acceptance criteria, and as a result the Company's level of procurement may continue to vary from quarter-to-quarter and year-to-year. The Company believes that its existing vascular tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for vascular tissues for the reasonably foreseeable future.

### *Orthopaedic Preservation Services*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 38	\$ 566	\$ 662	\$ 3,650
Orthopaedic revenues as a percentage of total revenues	0%	3%	1%	5%

Revenues from orthopaedic preservation services decreased 93% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. Pursuant to its agreement with RTI, CryoLife ceased marketing its orthopaedic tissue services as of June 30, 2008. For a commission, RTI can market and direct CryoLife to ship the Company's remaining orthopaedic tissues through December 31, 2008. These marketing efforts by RTI generated minimal revenues during the three months ended September 30, 2008.

Revenues from orthopaedic preservation services decreased 82% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. This decrease was primarily due to significant decreases in unit shipments of orthopaedic tissues, due to the complete cessation of the Company's marketing efforts as of June 30, 2008 as described above and due to the limited supply of orthopaedic tissues available for shipment during the first half of 2008, resulting from the Company's cessation of procuring and processing these tissues on January 1, 2007 and declining demand for the Company's orthopaedic tissues.

CryoLife expects that RTI's marketing efforts will generate only nominal amounts of orthopaedic tissue service revenues for the Company in the fourth quarter of 2008.

### *BioGlue*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 11,623	\$ 10,280	\$ 36,482	\$ 32,373
BioGlue revenues as a percentage of total revenues	43%	46%	46%	46%

Revenues from the sale of BioGlue increased 13% for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. This increase was primarily due to the aggregate impact of favorable product mix and a 9% increase in the number of BioGlue milliliters shipped, which increased revenues by 10%, and an increase in average selling prices, which increased revenues by 3%.

Revenues from the sale of BioGlue increased 13% for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. This increase was primarily due to the aggregate impact of favorable product mix and a 4% increase in the number of BioGlue milliliters shipped, which increased revenues by 10%, and an increase in average selling prices, which increased revenues by 3%.

The favorable product mix and volume increase for the three and nine months ended September 30, 2008 was primarily due to an increase in sales of BioGlue syringes in domestic and international markets, partially offset by a related decrease in BioGlue cartridge sales, resulting in an increase in the total number of milliliters sold as well as a favorable product mix as the newer syringe product commands a premium price over the older cartridge product. The increase in average selling prices for the three and nine months ended September 30, 2008 was primarily due to domestic list price increases that went into effect in January 2008.



Domestic revenues accounted for 70% and 72% of total BioGlue revenues for the three months ended September 30, 2008 and 2007, respectively. Domestic revenues accounted for 71% and 72% of total BioGlue revenues for the nine months ended September 30, 2008 and 2007, respectively.

The majority of the Company's foreign BioGlue revenues are denominated in British Pounds and Euros, and as such are sensitive to changes in exchange rates. In addition a portion of the Company's dollar-denominated BioGlue sales are made to customers in other countries who must convert local currencies into U.S. dollars in order to purchase BioGlue. As a result the Company's revenues in the fourth quarter of 2008 and in 2009 could be negatively impacted by changes in exchange rates from the weighted average exchange rates experienced by the Company in the prior year periods and by declining demand from foreign customers who may be impacted by changes in exchange rates.

**Other Medical Devices**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 616	\$ 265	\$ 1,017	\$ 723
Other medical devices revenues as a percentage of total revenues	2%	1%	1%	1%

Revenues from the sale of other medical devices increased 132% and 41% for the three and nine months ended September 30, 2008, respectively, as compared to the three and nine months ended September 30, 2007. The increase in revenues for the three and nine months ended September 30, 2008 was primarily due to sales of Hemostase MPH, which CryoLife began distributing during the second quarter of 2008. Hemostase MPH revenues for the three and nine months ended September 30, 2008 were \$549,000 and \$726,000, respectively.

Other medical device revenues in 2008 consisted of sales of Hemostase MPH, CardioWrap, and bioprosthetic devices. Other medical device revenues in 2007 consisted of sales of CardioWrap and bioprosthetic devices.

**Other Revenues**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues	\$ 377	\$ 268	\$ 691	\$ 580
Other revenues as a percentage of total revenues	1%	1%	1%	1%

Other revenues for the three months ended September 30, 2008 included revenues for research grants. Other revenues for the three months ended September 30, 2007 included revenues for research grants and revenues related to the licensing of the Company's technology to a third party.

Other revenues for the nine months ended September 30, 2008 and 2007 included revenues for research grants and revenues related to the licensing of the Company's technology to a third party.

In 2008, 2007, and 2005 CryoLife was awarded \$848,000, \$1.9 million, and \$930,000, respectively, in funding allocated from U.S. Congress Defense Appropriations Conference Reports, the ( 2007 DOD Grant ), ( 2006 DOD Grant ) and (the 2005 DOD Grant ), respectively. These grants were awarded for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. Grant revenues in 2008 and 2007 are related to funding under one or more of these grants for the development of BioFoam®. The 2008 Defense Appropriations Conference Report (the 2008 DOD Grant ) included \$1.7 million for the continued development of protein hydrogel technology. CryoLife anticipates applying for funding under this bill in late 2008 or in 2009. The Company does not currently know if it will be approved to receive funding under the 2008 DOD Grant or when decisions concerning the funding will be made.

Through September 30, 2008 CryoLife had received cash payments for all funds awarded under the 2005 and 2006 DOD Grants, and a portion of the 2007 DOD Grant, for a total of \$3.1 million. As of September 30, 2008 CryoLife had \$1.6 million in unspent cash advances under the grants recorded as cash and deferred revenues on the Company's Summary Consolidated Balance Sheet.

## Costs and Expenses

### *Cost of Preservation Services*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of preservation services	\$ 7,615	\$ 6,575	\$ 22,382	\$ 21,183
Cost of preservation services as a percentage of preservation services revenues	54%	58%	54%	59%

Cost of preservation services increased 16% and 6% for the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007, respectively. The increase in cost of preservation services for the three and nine months ended September 30, 2008 was primarily due to an increase in the volume of tissue shipments. This increase was partially offset by the favorable effect of lower write-downs recorded in the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007. Tissue write-downs included in cost of preservation services for the periods discussed above include write-downs due to the impairment of certain vascular and orthopaedic tissues and/or write-downs related to the Company's non-valved cardiac tissue costs that exceeded market value, as discussed in Critical Accounting Policies above.

Cost of preservation services as a percentage of preservation services revenues for the three and nine months ended September 30, 2008 decreased when compared to the three and nine months ended September 30, 2007 primarily due to increases in average service fees and the premium related to the Company's SynerGraft processed tissues, and to a lesser extent the decrease in tissue write-downs.

The Company anticipates that cost of preservation services as a percentage of preservation services revenues in 2008 may continue to be favorably impacted by shipments of the CryoValve SG, as CryoValve SG currently has and is expected to continue to have a premium fee over the standard processed CryoValve. However, there can be no assurance that the CryoValve SG will continue to command premium fees or that shipments of the CryoValve SG will continue to occur at material levels.

### *Cost of Products*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of products	\$ 2,028	\$ 1,615	\$ 5,860	\$ 5,444
Cost of products as a percentage of product revenues	17%	15%	16%	16%

Cost of products increased 26% and 8% for the three and nine months ended September 30, 2008 as compared to the three and nine months ended September 30, 2007, respectively. The increase in cost of products for the three and nine months ended September 30, 2008 was primarily due to \$281,000 and \$1.2 million, respectively, in write downs of other medical device inventory, and increased volume of BioGlue sales, partially offset by the favorable effect of changes in product mix, as sales volume decreased for higher cost bioprosthetic devices.

The current year write-downs of medical device inventory were primarily due to impairments in the value of product inventory for products that are not expected to ship prior to their expiration date. These write-downs were a result of changes in sales estimates for these products or delays in the expected launch of a new product.

Cost of products as a percentage of product revenues for the three months ended September 30, 2008 increased when compared to the three months ended September 30, 2007, primarily due to the medical device write downs discussed above, partially offset by an increase in BioGlue average selling prices and favorable product mix, as sales volume decreased for higher cost bioprosthetic devices. Cost of products as a percentage of product revenues for the nine months ended September 30, 2008 was comparable to the nine months ended September 30, 2007 as the unfavorable effect of the write-downs of medical device inventory were offset by the favorable effects of the increase in BioGlue average selling prices and favorable product mix, as sales volume decreased for higher cost bioprosthetic devices. The increase in average selling prices for the three and nine months ended September 30, 2008 is primarily due to price increases that went into effect on the majority of BioGlue products in January 2008.

#### *General, Administrative, and Marketing Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
General, administrative, and marketing expenses	\$ 12,072	\$ 11,240	\$ 36,497	\$ 34,417
General, administrative, and marketing expenses as a percentage of total revenues	45%	51%	46%	49%

The increase in general, administrative, and marketing expenses for the three and nine months ended September 30, 2008 was primarily due to increases in marketing expenses, including personnel costs, corporate advertising, and promotional materials to support the Company's expanding tissue service and product offerings and revenue growth. To a lesser extent, the increases in general, administrative, and marketing expenses were affected by the favorable effect of net changes in product liability accruals and decreases in professional fees and insurance costs, partially offset by an increase in stock compensation expense over the prior year periods.

General, administrative, and marketing expenses included stock based compensation expense of \$659,000 and \$2.0 million for the three and nine months ended September 30, 2008, respectively, and \$601,000 and \$1.5 million for the three and nine months ended September 30, 2007, respectively. General, administrative, and marketing expenses included \$786,000 in postemployment benefit expenses for the nine months ended September 30, 2007.

#### *Research and Development Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development expenses	\$ 1,186	\$ 1,098	\$ 3,938	\$ 3,134
Research and development expenses as a percentage of total revenues	4%	5%	5%	4%

Research and development spending for the three and nine months ended September 30, 2008 and 2007 included research on the Company's SynerGraft products and tissues, Protein Hydrogel Technologies ( PHT ), and tissue preservation technology. SynerGraft products and tissues include the Company's allograft and xenograft heart valves, vascular grafts, and ProPatch Soft Tissue Repair Matrix. PHT includes BioGlue, BioFoam, BioDisc®, and related products. Research and development spending in 2008 also included research on cold storage and preservation of internal organs.

The Company anticipates that research and development expenses for 2008 will exceed 2007, primarily due to increased spending on research related to BioFoam, BioDisc, cold storage and preservation of internal organs, and SynerGraft products and tissues.

---

***Other Costs and Expenses***

Interest expense was \$62,000 for the three months ended September 30, 2008, compared to \$178,000 for the three months ended September 30, 2007. Interest expense was \$201,000 for the nine months ended September 30, 2008, compared to \$518,000 for the nine months ended September 30, 2007. Interest expense for the three and nine months ended September 30, 2008 decreased primarily due to a decrease in line of credit borrowings as a result of the February 8, 2008 expiration and payoff of the balance due on the Company's prior credit agreement with Wells Fargo Foothill, Inc. The Company has maintained lower balances on its new line of credit with GE Capital entered into in March of 2008.

Interest income was \$92,000 for the three months ended September 30, 2008, compared to \$158,000 for the three months ended September 30, 2007. Interest income was \$285,000 for the nine months ended September 30, 2008, compared to \$360,000 for the nine months ended September 30, 2007. Interest income for the three and nine months ended September 30, 2008 and 2007 was primarily due to interest earned on the Company's cash, cash equivalents, marketable securities and restricted cash and investments.

The change in valuation of the embedded derivative feature of the Company's preferred stock was zero for the three and nine months ended September 30, 2008 as compared to an expense of zero and \$821,000 for the three and nine months ended September 30, 2007. The change in valuation of the Derivative for the nine months ended September 30, 2007 was primarily due to conversions of the Preferred Stock during the second quarter of 2007 in excess of amounts previously accrued.

The Company's income tax expense was \$235,000 and \$610,000 for the three and nine months ended September 30, 2008, respectively. The Company's income tax expense was \$55,000 and \$234,000 for the three and nine months ended September 30, 2007, respectively. Income tax expense in the current and prior year periods was primarily due to alternative minimum tax on the Company's taxable income in each period that cannot be offset by the Company's net operating loss carryforwards, state tax obligations, and foreign taxes on income of the Company's wholly owned European subsidiary.

The Company reassesses the recoverability of its deferred tax assets and the appropriate levels of the valuation allowance on a quarterly basis. In conducting this assessment, management considers a variety of factors, including Company estimates of taxable income for future years, as well as the reasons for the Company's operating losses in prior years, its recent improvements to profitability, and management's judgment as to the likelihood of continued profitability and expectations of future performance, and other factors. Due to the nature of the analysis required, if the Company's operations continue to be profitable, it is likely that all or a portion of the valuation allowance will be reversed. At the time of reversal, the Company will record a corresponding non-cash gain that is likely to have a material impact on the Company's results of operations during the period in which the reversal occurs. In periods following the reversal, the Company's effective income tax rate will be significantly higher than the effective income tax rate experienced in periods prior to the reversal.

**Seasonality**

The demand for the Company's cardiac preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school aged patients, who drive the demand for a large percentage of cardiac tissues processed by CryoLife. In recent years the growth rate of CryoLife's cardiac business has obscured the seasonal trend, but the Company believes that this seasonal trend will be more apparent in future years.

The demand for the Company's human vascular preservation services does not appear to be seasonal.

The demand for BioGlue appears to be seasonal, with a slight decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be



due to the summer holiday season in Europe and fewer surgeries being performed on adult patients in the summer months in the U.S. The Company will continue to evaluate the seasonal nature of BioGlue sales.

## **Liquidity and Capital Resources**

### ***Net Working Capital***

At September 30, 2008 net working capital (current assets of \$72.9 million less current liabilities of \$21.4 million) was \$51.5 million, with a current ratio (current assets divided by current liabilities) of 3 to 1, compared to net working capital (current assets of \$65.5 million less current liabilities of \$24.7 million) of \$40.8 million, with a current ratio (current assets divided by current liabilities) of 3 to 1 at December 31, 2007.

### ***Overall Liquidity and Capital Resources***

The Company's primary cash requirements for the nine months ended September 30, 2008 arose out of the reclassification of cash equivalents to long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed below, payment of the balance due under the Company's prior credit agreement which expired in February 2008, and general working capital needs, including annual payments of royalties and bonuses accrued in the prior year, capital expenditures for facilities and equipment, and funding of research and development projects. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

In March of 2008 CryoLife entered into a credit facility with GE Capital, which provides for up to \$15.0 million in revolving credit for working capital, acquisitions and other corporate purposes. The GE Credit Agreement does not require that funds be made available to the Company in a timely fashion when requested or at all, and if the current financial and credit liquidity crisis continues or worsens, GE may be unable or unwilling to lend money pursuant to this agreement. As of September 30, 2008 the outstanding balance under this agreement was \$315,000. As of April 15, 2008, as required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement, and as such have been recorded as the long-term asset restricted money market funds on the Company's Summary Consolidated Balance Sheet.

The Company's cash equivalents include advance funding received under the 2006 and 2007 DOD Grants for the continued development of protein hydrogel technology. As of September 30, 2008 \$1.6 million of cash equivalents were recorded on the Company's Summary Consolidated Balance Sheet related to the 2006 and 2007 DOD Grants. These funds must be used for the specified purposes.

CryoLife is actively pursuing three key strategies designed to generate revenue and earnings growth in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These three strategies are: (i) identify and evaluate acquisition opportunities of complementary product lines and companies; (ii) license Company technology to third parties for non-competing uses; and (iii) analyze and identify underperforming assets for potential sale or disposal. Management's actions related to this Board directive are ongoing and any material acquisition of complementary product lines or companies would likely require additional debt or equity financing. In addition the GE Credit Agreement contains certain restrictions on the Company's ability to effect an acquisition for cash.

The Company believes that its anticipated cash from operations, existing cash, cash equivalents, marketable securities, and borrowing availability will enable the Company to meet its operational liquidity needs for at least the next twelve months.

### ***Product Liability Claims***

As discussed in Critical Accounting Policies above, as of September 30, 2008 the Company had a \$330,000 accrual for the pending tissue processing liability lawsuit. The timing and amount of actual future payments with

respect to product and tissue processing liability claims is dependent on when and if judgments are rendered and/or settlements are reached. Should payments be required, the Company's portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach resolution of outstanding claims in order to minimize the potential cash payout.

As discussed in Critical Accounting Policies above, at September 30, 2008 the Company had accrued a total \$5.2 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to September 30, 2008 and had recorded a receivable of \$1.7 million representing estimated amounts to be recoverable from the Company's insurance carriers with respect to such accrued liability. Further analysis indicated that the liability could be estimated to be as high as \$10.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$5.2 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

#### ***Net Cash from Operating Activities***

Net cash provided by operating activities was \$6.7 million for the nine months ended September 30, 2008 as compared to \$4.9 million for the nine months ended September 30, 2007. The increase in cash provided by operating activities from the prior year period was primarily due to an increase in net income generated during the period, largely offset by increases in working capital needs due to the timing of receipts and payments in the ordinary course of business.

The Company uses the indirect method to prepare its cash flow statement, and accordingly, the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2008 the Company's \$10.2 million net income included non-cash items that generated favorable and unfavorable adjustments to net income. These included favorable adjustments of \$3.3 million in depreciation and amortization expense, \$2.1 million in non-cash compensation, primarily related to expense for stock options and stock awards, and \$1.4 million in write-downs for impairment of deferred preservation costs and inventory.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2008 these unfavorable changes included \$9.0 million due to the increase in deferred preservation costs and inventories, \$1.5 million due to the increase in accounts receivable, and \$732,000 due to the timing difference between making cash payments and the expensing of assets, including the prepayment of insurance policy premiums.

#### ***Net Cash from Investing Activities***

Net cash used in investing activities was \$3.9 million for the nine months ended September 30, 2008, as compared to \$1.9 million for the nine months ended September 30, 2007. The current year cash used was primarily due to \$5.0 million in cash equivalents that was reclassified as long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed above, \$1.4 million in capital expenditures and \$1.1 million in purchases of marketable securities, partially offset by \$3.6 million in sales and maturities of marketable securities.

#### ***Net Cash from Financing Activities***

Net cash used in financing activities was \$2.2 million for the nine months ended September 30, 2008, as compared to net cash provided of \$1.3 million for the nine months ended September 30, 2007. The current year cash used was primarily due to \$4.6 million in principal payments on debt, and \$865,000 in principal payments on notes payable, partially offset by \$1.8 million in proceeds from the exercise of options and the issuance of stock, \$1.3 million in proceeds from the financing of insurance policies, and \$428,000 in proceeds from debt issuance. The principal payments on debt were primarily due to the payoff of the balance due under the Company's prior credit agreement which expired in February 2008.

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of September 30, 2008 are as follows (in thousands):

	Total	Remainder of 2008	2009	2010	2011	2012	Thereafter
Operating leases	\$ 17,299	\$ 623	\$ 2,494	\$ 2,373	\$ 2,331	\$ 2,329	7,149
Compensation payments	3,035		1,050		993	992	
Purchase commitments	736	617	119				
Royalty payments	611	611					
Insurance premium obligations	543	543					
Line of credit	315				315		
Capital lease obligations	101	13	53	35			
Other obligations	332	213	95	10	10	4	
<b>Total contractual obligations</b>	<b>\$ 23,972</b>	<b>\$ 2,620</b>	<b>\$ 3,811</b>	<b>\$ 2,418</b>	<b>\$ 3,649</b>	<b>\$ 3,325</b>	<b>\$ 7,149</b>

The Company's operating lease obligations result from the lease of land and buildings that comprise the Company's corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The Company's compensation payment obligations represent estimated cash payments to be made for its 2008 performance based bonus plans and estimated payments for post employment benefits for the Company's Chief Executive Officer (CEO). The timing of the post employment benefits is based on the December 2010 expiration date of the CEO's agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The Company's purchase commitments include obligations from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production and contractual payments for licensing computer software. The Company's insurance premium obligations represent installment payments related to payment plans and notes payable from the second quarter 2008 renewal and financing of certain of the Company's insurance policies. The Company's royalty payments are related to BioGlue revenues.

The line of credit obligation results from the Company's borrowing of funds under the GE Credit Agreement. The timing of this obligation is based on the agreement's March 25, 2011 expiration date, at which time the outstanding principal balance will be due. The table above does not include interest and fees on the line of credit, as these can vary due to changes in the level of borrowings and changes in interest rates.

The Company's capital lease obligations result from the financing of certain of the Company's equipment. The Company's other obligations contain various items including payments to support research and development activities and other items as appropriate.

The schedule of contractual obligations above excludes: (i) obligations for estimated product liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation; (ii) additional payments of up to \$1.2 million related to licensing of technology from a third party which are contingent upon the outcome of the Company's research activities; (iii) \$1.5 million of the \$1.6 million in advance funding received under the 2006 DOD Grant for which a specific timetable of spending has not been established and for which there are no current agreements or contracts in place; and (iv) any estimated liability for uncertain tax positions, currently estimated to be \$2.2 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made by any taxing authorities.

*Capital Expenditures*

Capital expenditures for the nine months ended September 30, 2008 were \$1.4 million compared to \$581,000 for the nine months ended September 30, 2007. Planned capital expenditures for the remainder of 2008 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business.

---

## FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well as estimates and assumptions made by and information currently available to management. The words could, may, will, would, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, and other similar words identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in this filing.

All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

- The Company's ability to increase, and methods for increasing, BioGlue, Hemostase MPH, and preserved tissue market penetration;
- Potential BioGlue product line extensions;
- The expected benefits of surgical adhesives and sealants;
- Expected usage of SynerGraft technology;
- The anticipated competitive advantages and potential impact on revenues of SynerGraft;
- Expectations that CryoValve SG will continue to command premium fees over the standard processed CryoValve;
- Expected continued increase in 2008 of cardiac preservation service revenues as a result of shipments of CryoValve SG;
- Expectations regarding the impact of CryoValve SG pulmonary heart valve on cost of preservation services as a percentage of preservation services revenues;
- Information regarding the expected SynerGraft post-clearance study;
- The expected outcome of lawsuits filed by or against the Company;
- The Company's estimated future liability for existing product liability lawsuits and for product liability claims incurred but not yet reported;
- Expectations regarding, and possible increases in the cost and retention of, future insurance coverage;
- Anticipated future demand for cardiac and vascular tissues;
- Management's beliefs that current cardiac and vascular procurement levels are sufficient to support future demand;
- The Company's continued use of human tissue implant data;
- The Company's competitive position, including the impact of price increases;
- Competitive advantages offered by the Company's patents, trade secrets, trademarks, and technology licensing rights;
- The anticipated impact of the Company's strategic plans and its ability to implement them;
- Commercialization plans and potential benefits of our products in development;
- Expectations regarding capital expenditures;
- The amount and type of future research and development expenses;
- The ability to expand the Company's service and product offerings;
- Expected seasonality trends;
- Expected impact of adoption of new accounting pronouncements;
- Anticipated impact of changes in interest rates and foreign currency exchange rates;
- Expected decreases in revenues from the distribution of orthopaedic tissue;
- Expected increases in grant revenues;
- The receipt of governmental grants for BioFoam development;

The Company's plans to apply for further federal funding for the development of BioFoam;  
The adequacy of the Company's financial resources;  
Current intentions not to pay cash dividends on our common stock;  
Current intentions to retain future earnings for capital requirements;  
Expectations regarding the use of net operating loss carryforwards;  
Expectations regarding the ability of the Company to distribute Hemostase MPH;  
Expectations regarding the potential reversal of the valuation allowances on the Company's deferred tax assets and subsequent changes in our effective income tax rate;  
Issues that may impact the Company's future financial performance and cash flows;  
Estimated compensation payment obligations related to 2008 performance based bonus plans and post employment benefits; and  
Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risks set forth under "Risk Factors" in Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2007 and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

#### **RISKS AND UNCERTAINTIES**

See Part II, Item 1A., "Risk Factors" for a discussion of risks and uncertainties which might impact the Company's forward-looking statements contained in this Form 10-Q, and the trading value of our common stock.

---

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

The Company's interest income and expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of \$15.0 million and restricted money market funds and investments of \$5.6 million and interest paid on the Company's variable rate line of credit as of September 30, 2008. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended September 30, 2008, affecting the Company's cash and cash equivalents, restricted money market funds and investments, and line of credit would not have a material impact on the Company's financial position, results of operations, or cash flows.

***Foreign Currency Exchange Rate Risk***

The Company has balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. dollar equivalent of cash or funds that the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result the Company could be required to record these changes as gains or losses on foreign currency translation.

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a majority of the Company's foreign BioGlue revenues are denominated in British Pounds and Euros. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. dollar equivalent of net income from transactions conducted in other currencies. As a result the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

Changes in exchange rates that have occurred since September 30, 2008 as well as any further material adverse fluctuations in exchange rates could materially and adversely impact the Company's results of operations, financial position, and cash flows for the fourth quarter of 2008 and 2009. Had the exchange rates in effect on October 27, 2008 been in effect for the nine months ended September 30, 2008, the Company's revenues would have been approximately \$1.0 million lower than those actually reported. This effect, primarily related to the Company's BioGlue revenues, would have been largely offset by lower general, administrative, and marketing expenses denominated in British Pounds and Euros.

The change in exchange rates from September 30, 2008 through October 27, 2008 plus an additional 10% adverse change when compared to (i) the rates in effect on September 30, 2008 affecting the Company's balances denominated in foreign currencies and (ii) the weighted average exchange rates experienced by the Company for the nine months ended September 30, 2008 affecting the Company's revenue and expense transactions denominated in foreign currencies, would have had a net unfavorable impact of approximately \$674,000.

**Item 4. Controls and Procedures.**

The Company's management, including the Company's President and Chief Executive Officer ( CEO ) and the Company's Executive Vice President, Chief Operating Officer, and Chief Financial Officer ( CFO ), does not expect that its disclosure controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake.

Based upon the Company's most recent disclosure controls evaluation as of September 30, 2008, the CEO and CFO have concluded that the Company's disclosure controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended September 30, 2008 there were no changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

## **Part II - OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

On October 1, 2008, Tenaxis, Inc. filed a nullity action against one of CryoLife's BioGlue patents in Federal Patent Court in the State of Bavaria in the Federal Republic of Germany that seeks to invalidate CryoLife's patent No. EP 0 650 512, which is our main European patent for BioGlue. The Company will defend the lawsuit.

In October 2008, the Company filed a patent infringement action in a Patent Court in the State of North Rhein-Westphalia in Düsseldorf in the Federal Republic of Germany. This complaint alleges that Tenaxis, Inc. is infringing the Company's BioGlue patent No. EP 0 650 512 in Germany by selling a surgical adhesive. The complaint has not yet been served on Tenaxis, Inc. The Company is seeking an injunction, damages, and a list of customers to which Tenaxis has sold or is planning to sell its products.

Other than the item discussed above, there have been no material changes from the legal proceedings previously discussed in the Company's Form 10-Q for the quarter ended March 31, 2008 in response to Part II, Item 1 thereof.

### **Item 1A. Risk Factors.**

## **RISK FACTORS**

### **Risks Relating To Our Business**

#### **We Are Significantly Dependent On Our Revenues From BioGlue® And Are Subject To A Variety Of Risks Affecting This Product.**

BioGlue is a significant source of our revenues. Should the product be the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices, or if a competitor's product obtains greater acceptance, or our rights to manufacture and market this product are challenged, the result could have a material adverse effect on our business, financial position, results of operations, and cash flows. Also, we have only two suppliers of bovine serum albumen, which is necessary for the manufacture of BioGlue. Furthermore, we presently have only one supplier for our BioGlue syringe. If we lose one or more of these suppliers, our ability to manufacture and sell BioGlue could be adversely impacted. We cannot be sure that we would be able to replace any such loss on a timely basis, if at all. In addition our U.S. patent for BioGlue expires in 2012 and our patents in the rest of the world expire in 2013. Following expiration of these patents, competitors may utilize the inventions disclosed in the BioGlue patents in competing products, which could materially reduce our revenues and income from BioGlue. See **Uncertainties Related To Patents And Protection of Proprietary Technology May Adversely Affect The Value Of Our Intellectual Property**, below.



---

**We May Receive A Form 483 Notice Of Observations, A Warning Letter, Or Other Similar Communication From The FDA And We May Be Unable To Address The Concerns Raised By The FDA In Such Correspondence or Communication, Or Addressing The Concerns May Be Costly Or Could Materially and Adversely Affect Our Operations.**

The FDA has issued Form 483 Notices of Observations ( Form 483 ) and Warning Letters to us in the past that have noted deficiencies in our operations, including process validation, complaint handling, and reporting, and analysis of certain testing results, among other items. Although we have had positive FDA inspections recently, we could still be subject to an FDA inspection that results in a Form 483. If the FDA deems our responses to a Form 483 unsatisfactory, it could take further action, such as issuing us a Warning Letter, or in the alternative even before issuing a Form 483, the FDA could issue a Warning Letter directly to us or other similar communication. Corrective actions taken by us to address these regulatory actions could materially and adversely affect our business, results of operations, financial position, or cash flows. If we are unable to implement adequate corrective actions required by the Warning Letter or similar request made by the FDA, the FDA could institute additional recalls of tissues or products, require us to perform additional tests, begin to require prescriptions for tissues or products where they are not currently required, halt the shipping or processing of tissues or products, or require additional approvals for marketing our tissue services or products, which could materially and adversely affect our revenues, profitability, and cash flows.

**SynerGraft® Processed Human Pulmonary Heart Valves and Other SynerGraft Products May Not Be Accepted By The Marketplace.**

CryoValve® SG pulmonary heart valve may not perform as well as expected or provide all of the benefits anticipated by the marketplace and, as a result, the Company may not be able to continue to process a portion of its human pulmonary valves with its SynerGraft technology. In that event the Company would need to return to processing most or all of its pulmonary heart valves without the SynerGraft technology, which could significantly reduce the expected benefits of the SynerGraft technology. In addition other products being developed for commercialization by CryoLife that utilize the SynerGraft process, such as ProPatch®, CryoLife's soft tissue repair matrix for use in hernia repair and certain orthopaedic related conditions, may not provide the anticipated benefits or otherwise achieve marketplace acceptance.

**SynerGraft Processed Human Pulmonary Heart Valves Have A One Year Shelf Life.**

We are currently using the SynerGraft technology for a portion of our human pulmonary heart valve processing pursuant to the 510(k) clearance we have received for the SynerGraft treated valves. Our SynerGraft pulmonary heart valves currently have a one year shelf life, whereas our non-SynerGraft processed pulmonary heart valves have a five year shelf life. We are currently in discussions with the FDA to extend the shelf life of our SynerGraft pulmonary heart valves. We do not know when the shelf life of the SynerGraft pulmonary heart valves may be extended, if at all. Accordingly, if we do not implant our SynerGraft pulmonary heart valves within one year of cryopreservation, we may be required to discard these valves, and as a result we may lose more tissues than before we started processing pulmonary heart valves with the SynerGraft technology, which could have a material adverse effect on our revenues, profitability, and cash flows.

**We Are Dependent On The Availability Of Sufficient Quantities Of Tissue From Human Donors.**

The success of our tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. We rely primarily upon the efforts of third party procurement agencies, tissue banks (most of which are not-for-profit), and others to educate the public and foster a willingness to donate tissue. If the supply of donated human tissue is materially reduced, this would restrict our growth and adversely affect our business, results of operations, financial condition, and cash flows.

**Our CryoValve SG Pulmonary Heart Valve Post-clearance Study May Not Provide Expected Results.**

At the FDA's request, we are conducting a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process used to process the CryoValve SG pulmonary heart valve. We expect the data to be collected to include long-term safety and hemodynamic function, immune response, and explant

analysis. Although we believe that this information may help us ascertain whether the SynerGraft process reduces the immune response of the transplanted heart valve and allows for the collagen matrix to recellularize with the recipient's own cells, it is possible that the results of the study will not be as expected. If this study shows that the SynerGraft process does not reduce immune response and/or cause the collagen matrix to recellularize with the recipient's cells, we may be unable to realize some or all of the long-term benefits that we anticipated for the use of this process.

**The FDA Has Previously Issued A Recall Of Certain Of Our Products And Has The Ability To Inspect Our Facilities, Suspend Our Operations, And Issue A Recall Of Our Products In The Future.**

On August 13, 2002 we received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the "FDA Order"). Pursuant to the FDA Order, we placed non-valve cardiac, vascular, and orthopaedic tissue processed since October 3, 2001 on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition we ceased processing non-valved cardiac and vascular tissues until mid-September 2002 and ceased processing orthopaedic tissues until 2003. The FDA Order resulted in the destruction of much of our tissue, required that we adjust revenue for tissue recall returns, curtailed our processing activities, and subjected us to intense FDA scrutiny and additional regulatory requirements that increased costs. We also suffered decreased revenues due to lack of processing ability and decreased market demand for our services. These challenges reduced our revenues, increased our costs to process tissues and our operating expenses, and strained management resources and available cash. Although we resumed processing and distribution of the types of tissues subject to the FDA Order and resolved many of the product liability suits pending against us, we incurred losses and did not produce cash from operations for many years. Any future recalls or other regulatory action by the FDA would likely have a material adverse impact on our revenues, profitability, and cash flows.

The FDA can reinspect our facilities, review complaints against us, monitor the efficacy of our products and the claims we make regarding our products' benefits, and issue reports to us on areas that require improvement. If the FDA believes that we are not responsive to their requests for any suggested improvement or that our products are not in compliance with regulatory norms, the FDA has the ability to suspend our operations and issue an order for the recall of any or all of our products. If the FDA issues such an order, our revenues, profitability, and cash flows could be materially and adversely affected.

**Our Products And The Tissues We Process Allegedly Have Caused And May In The Future Cause Injury To Patients, And We Have Been And May Be Exposed To Product Liability Claims And Additional Regulatory Scrutiny As A Result.**

The processing, preservation, and distribution of human tissue, bovine tissue products, porcine tissue products, and the manufacture and sale of medical devices entail inherent risks of medical complications for patients and have resulted and may result in product liability claims against us. Plaintiffs have asserted that our tissue or medical devices have caused a variety of injuries, including death. When patients are injured, die, or have other adverse results following procedures using our tissue or medical devices, we have been and may be sued and our insurance coverage has been and may be inadequate. Adverse judgments and settlements in excess of our available insurance coverage could materially and adversely affect our business, financial position, results of operations, and cash flows.

As a result of medical complications that are alleged to have been caused by or occur in connection with medical procedures involving our tissue or medical devices, we have been and may be subject to additional FDA and other regulatory scrutiny and inspections. For example, shortly after the FDA Order, the FDA posted a notice, now archived, on its website stating its concerns regarding our heart valve preservation services. As a result, some surgeons and hospitals decided not to use our heart valves. Cautionary statements from the FDA or other regulators regarding our tissue services or products, changes to our labeling, or required prominent warnings or negative reviews from the FDA or regulators of our processing and manufacturing facilities have decreased and may in the future decrease demand for our tissue services or products and could reduce our revenues and materially and adversely affect our business, financial position, results of operations, and cash flows.

In addition to the recall resulting from the FDA Order, we have in the past suspended or recalled, and in the future may have to suspend the distribution of or recall, particular types of tissues as a result of reported adverse

events in connection with our tissues. Suspension of the distribution of, or recall of, our tissue services or products could materially and adversely affect our revenues, profitability, and cash flows.

**Key Growth Strategies Identified As A Result Of Our Strategic Review May Not Generate The Anticipated Benefits.**

In January 2006 we engaged a financial advisor to assist our management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. As a result of this review, the Board of Directors has directed management to actively pursue three key strategies to generate revenue and earnings growth in addition to continuing to focus on growing our business and leveraging our strengths and expertise in our core marketplaces. These three strategies are:

- Identifying and evaluating acquisition opportunities of complementary product lines and companies,
- Licensing our technology to third parties for non-competing uses, and
- Analyzing and identifying underperforming assets for possible sale or other disposition.

Although management has begun to implement these strategies, we cannot be certain that they will ultimately enhance shareholder value.

**Our Ability To Borrow Under Our Credit Facility May Be Limited**

Our credit facility contains a number of affirmative covenants that we must satisfy before we can borrow. For example, we must satisfy specified leverage ratios, and there are also increasing levels of adjusted earnings before interest taxes depreciation and amortization ( EBITDA ) under the credit facility that we have covenanted to maintain during the term of the credit facility. Failure to satisfy any of these requirements could limit our borrowing ability and materially and adversely affect our liquidity. In addition, our credit facility does not obligate the lender to make funds available to us in a timely fashion or at all, even when requested. See Financial and Credit Crisis May Adversely Affect Our Ability to Borrow Money or Raise Capital , below.

**Our Credit Facility Limits Our Ability To Pursue Significant Acquisitions.**

Our credit facility prohibits mergers and acquisitions other than certain permitted acquisitions. Permitted acquisitions include non-hostile acquisitions that have been approved by the Board of Directors and/or the stockholders of the target company, if after giving effect to the acquisition, there is no event of default under the credit facility and there is still at least \$1.5 million available to be borrowed under the credit facility. The total consideration that we pay or are obligated to pay for all acquisitions consummated during the term of the credit facility, less the portion of any such consideration funded by the issuance of common or preferred stock, may not exceed a specified aggregate amount. As a result, our ability to consummate acquisitions, and fully realize our growth strategy, may be materially and adversely affected.

**The Financial and Credit Liquidity Crisis May Adversely Affect Our Ability to Borrow Money or Raise Capital.**

If the financial and credit liquidity crisis were to continue or become more severe it may impact our ability to obtain money under our credit facility. Our credit facility does not require that funds be made available to us in a timely fashion when requested or at all, and if the current financial and credit liquidity crisis continues or worsens, our lender may be unable or unwilling to lend money pursuant to our line of credit. In addition, if we determined that it was appropriate or necessary to raise capital in the future, the financial and credit liquidity crisis, if it continues or worsens, may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable. If we were unable to use our line of credit or raise funds through debt or equity markets it could materially and adversely affect our liquidity or our ability to follow our key growth strategies outlined by the board of directors.

**There Are Limitations On The Use Of Our Net Operating Loss Carryforwards.**

We estimate that as of our last measurement date, December 31, 2007, we had approximately \$37.0 million in U.S. Federal net operating loss carryforwards, which could be used to offset future taxable income. These carryforwards begin to expire in the 2023 tax year. We may be unable to generate enough profits, if any, prior to their expiration to utilize our net operating loss carryforwards.

In addition, the amount of net operating loss carryforwards that we can utilize on an annual basis is capped after an ownership change within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended. Accordingly, a change in control of our Company within the meaning of Section 382 could substantially reduce the annual benefit of our net operating loss carryforwards and could, thereby, result in a portion of our net operating loss carryforwards expiring unused.

**Continued Deflation Of Foreign Currencies Relative To The U.S. Dollar Could Materially and Adversely Impact Our Business**

The majority of our foreign BioGlue revenues are denominated in British Pounds and Euros, and as such are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated BioGlue sales are made to customers in other countries who must convert local currencies into U.S. dollars in order to purchase BioGlue. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. The recent devaluation of British Pounds and Euros in relation to the U.S. dollar, should it continue or accelerate, or deflation of other currencies which affect our customers could materially reduce our fourth quarter 2008 and 2009 BioGlue revenue growth or could result in a material decrease in revenues in these periods as compared to the comparable prior periods. Should this occur, it could have a material and adverse impact on our revenues, profitability and cash flows.

**Regulatory Action Outside Of The U.S. Has Affected Our Business In The Past And May Also Affect Our Business In The Future.**

After the FDA issued the FDA Order, discussed above, Health Canada also issued a recall of the same types of tissue. In addition, other countries have made inquiries regarding the tissues that we export, although these inquiries are now, to our knowledge, complete. In the event other countries raise additional regulatory concerns, we may be unable to export tissues to those countries. Regulatory concerns could also be raised regarding the other products we market internationally, including BioGlue. Revenue from international human tissue preservation services was approximately \$896,000, \$572,000, and \$193,000 for the years ended December 31, 2007, 2006, and 2005, respectively, and approximately \$898,000 for the nine months ended September 30, 2008. International revenue from product sales, which includes international BioGlue revenue, was approximately \$12.8 million, \$11.3 million, and \$10.2 million for the years ended December 31, 2007, 2006, and 2005, respectively, and approximately \$10.9 million for the nine months ended September 30, 2008. Loss of all or a material portion of our international revenues would have a material adverse impact on our revenues, profitability, and cash flows.

**Physicians Have Been And May Continue To Be Reluctant To Implant Our Preserved Tissues Or Use Our Other Products.**

Some physicians or implanting institutions have been reluctant to choose our preserved tissues for use in implantation, due to a perception that the tissue may not be safe or a belief that the implanting physician or hospital may be subject to a heightened liability risk if our tissues are used. In addition, for similar reasons, some hospital risk managers have not allowed implanting surgeons to utilize our tissues when alternatives are available. Several risk managers and physicians have refused to use our products due to these concerns. These conditions have materially and adversely affected demand for our preserved human tissues. If these conditions persist, our results of operations and cash flows will continue to be adversely affected. If additional implanting hospitals or physicians representing significant revenues refuse to use tissues that we preserve or our other products, including BioGlue, and we are unable to replace the revenues lost, our revenues and profitability would be materially and adversely affected.

**Our Failure To Adequately Comply With Government Regulations Could Result In Loss Of Revenues And Customers As Well As Additional Compliance Expense.**

The FDA, certain international governments, and some states regulate the facilities and processes that we use. For example, the FDA, pursuant to regulations it promulgated under the Public Health Service Act, currently regulates human tissue. These regulations establish requirements for donor testing and screening of human tissue and record keeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. The FDA has also implemented good tissue practice regulations akin to good manufacturing practices, which must be followed by tissue banks and processors of human tissue. These regulations increase regulatory oversight of CryoLife and other processors of human tissue. The FDA also regulates BioGlue through its medical device regulations. These medical device regulations include the establishment of requirements for manufacturer registration, good manufacturing practices through the Quality System Regulations, premarket approval, and medical device reporting.

Our facilities are subject to periodic inspection by the FDA, state, and international regulatory authorities to ensure our compliance with applicable laws and regulations. Certain of our facilities and processes are subject to international standards set by the International Organization for Standardization with respect to which our compliance is reviewed by our Notified Body. If we fail to comply with these laws and regulations, we can be subject to sanctions, such as written observations of deficiencies made following inspections, warning letters, product recalls, fines, product seizures and consent decrees, all of which would be made available to the public. Such actions and publicity could affect our ability to sell our products and services. In the past, the FDA has sent us notifications and warning letters relating to deficiencies in our compliance with FDA requirements. We were required to take measures to respond, including labeling our processed tissue with a warning. We also were subject to the FDA Order, which decreased our revenues, increased our processing costs, and materially and adversely affected our business, financial position, results of operations, and cash flows. We cannot be certain that the FDA, or state or international regulatory authorities will not request that we take additional steps to correct deficiencies that may be raised in the future. Correcting any such deficiencies could materially and adversely affect our business.

**We Have Experienced Operating Losses And Negative Cash Flows, And We Must Continue To Address The Underlying Causes In Order To Continue To Operate Profitably And Generate Positive Cash Flows.**

Due principally to factors mentioned above, we suffered net losses in the years ended December 31, 2002 through 2005 and generated negative operating cash flow each year in the five year period ended December 31, 2006. There is no guarantee that we can continue to address the causes of our previous losses.

**Our Existing Insurance Policies May Not Be Sufficient To Cover Our Actual Claims Liability.**

Our products and the tissues we process allegedly have caused and may in the future cause injury to patients using our products or tissues and we have been and may be exposed to product liability claims.

Following the FDA Order, product liability lawsuits increased to unprecedented numbers for us. These claims involved assertions that infections and related morbidity, including death, were the result of inadequacies in our procedures. We maintain claims-made insurance policies to mitigate our financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

As of September 30, 2008, we know of one pending lawsuit against us, arising out of our allograft orthopaedic tissue preservation services. We believe that our product liability insurance covers this lawsuit. In addition other parties have made complaints against us that may result in lawsuits in future periods. We ceased accepting orthopaedic tissue for processing in January 2007.

Our September 30, 2008 Summary Consolidated Balance Sheet reflects a liability of approximately \$330,000 for the estimated cost of resolving this claim. The amount recorded was an estimate and does not reflect actual

settlement arrangements or final judgments, the latter of which could include punitive damages, nor does it represent cash set aside for the purpose of making payments. This balance sheet also reflects a \$5.2 million liability which is included as a component of accrued expenses of \$2.6 million and other long-term liabilities of \$2.6 million for the estimated cost of resolving unreported product liability claims. We believe that the liability could be estimated to be as high as \$10.3 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of September 30, 2008, \$1.7 million of the accrual for unreported liability claims would be recoverable under our insurance policies. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to September 30, 2008. Actual results may differ from this estimate. Our product liability insurance policies do not include coverage for any punitive damages.

Several putative class action lawsuits were filed in July through September 2002 against us and certain of our officers, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, based on a series of purportedly materially false and misleading statements to the market. On July 21, 2005 we reached an agreement in principle to settle the securities class action lawsuit and the settlement became final later in the year. In August 2002 and January 2003 purported shareholder derivative actions were filed. A settlement was also reached in those cases and became final in 2005. Our insurance proceeds were insufficient to fund the costs of defending and settling the securities class action and derivative lawsuits.

If we are unsuccessful in arranging acceptable settlements of current or future product liability, or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more claims, in which we are a defendant, whether now pending or hereafter arising, should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve the outstanding or any future claims, this will materially and adversely affect our financial position, results of operations, and cash flows. Further, if the costs of pending or incurred but unreported product liability claims exceed our current estimates, our business, financial position, and results of operations may be materially and adversely affected. If we do not have sufficient resources to pay the claims against us, we may be forced to cease operations or seek protection under applicable bankruptcy laws.

#### **We May Be Unable To Obtain Adequate Insurance At A Reasonable Cost, If At All.**

If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product liability claims. Additionally, insurance rates may be significantly higher than in the past, and insurers may provide less coverage, which may adversely impact our profitability. In addition, should we be subject to liability, whether imposed by a court or the result of a settlement that results in a large insurance claim, our insurance rates could increase significantly. Our current product liability insurance policy is a six-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

#### **We May Be Unable To Successfully Market Hemostase MPH.**

Part of our plans for future growth involve anticipated revenues from the sale of Hemostase MPH, a private label hemostatic agent which we currently market, pursuant to a distribution agreement, for use in cardiac and vascular surgery in the U.S. and for cardiac, vascular, and general surgery, other than orthopaedic and ear, nose and throat surgery, in certain international markets, subject to certain exclusions. Our ability to successfully market Hemostase MPH is subject to a number of risks, including:

- The possibility that surgeons may not accept Hemostase MPH,
- We may be unable to effectively leverage our existing sales force to market Hemostase MPH,
- Hemostase MPH may not perform as expected or provide all expected benefits, and
- Other distributors of the Hemostase MPH product may interfere with or otherwise impede our ability to market the product to new or existing customers.

**Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Affect The Value Of Our Intellectual Property.**

We own several patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own. We also cannot be certain that if anyone does make such a challenge, that we will be able to successfully defend that challenge. We may have to incur substantial litigation costs to uphold the validity and prevent infringement of a patent or to protect our proprietary technologies and methods. Furthermore, we cannot be certain that competitors will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of such technologies. We cannot be sure that our proposed technologies will not infringe patents or other rights owned by others, or that others will not infringe our patents.

We have filed suit in Germany against Tenaxis, Inc. because we believe that Tenaxis is infringing one of our BioGlue patents in Germany. This company has filed a separate suit to nullify this same BioGlue patent in Germany. Should we be unsuccessful in our lawsuit regarding infringement of our BioGlue patent or in prohibiting any other infringements of our patents, or should this nullity lawsuit filed by Tenaxis be successful, or the validity of our patents be successfully challenged by a third party, our revenues and profitability could be materially and adversely affected. We continue to investigate potential infringements of our U.S. BioGlue patents.

We protect our proprietary technologies and processes in part by confidentiality agreements with our collaborative partners, employees, and consultants. We cannot be sure that these entities and persons will not breach these agreements, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently discovered by competitors. If any of these events occur, they could result in our loss of the economic benefits associated with our key products and services and could materially and adversely affect our business, financial position, results of operations, and cash flows.

**Uncertainties Related To Patents and Protection Of Proprietary Technology For Products Distributed By CryoLife May Adversely Affect The Ability of CryoLife To Distribute Those Products.**

We distribute two products, Hemostase MPH and CardioWrap, that are manufactured by third parties. These third parties have patents, licenses, and proprietary technologies that give their products competitive advantages. We cannot be certain that no one will challenge the validity or enforceability of any patent that they own. Our contracts require that these third parties pursue infringements of patents owned or licensed by them for the products that we distribute. We may choose to assist our third party manufacturers and may incur substantial costs in any efforts to uphold the validity and prevent infringement of a patent or to protect proprietary technologies and methods. We cannot be certain that if anyone does make such a challenge, that these third parties will be able to successfully defend that challenge, with or without our assistance. Furthermore, we cannot be certain that competitors will not independently develop similar technologies, duplicate technologies, design around the patented aspects of such technologies, or attempt to duplicate their proprietary technologies that have no patent protection. In addition, we cannot be sure that these third parties' technologies will not infringe patents or other rights owned by others, or that others will not infringe these third parties' patents or use their proprietary rights inappropriately.

We believe that an entity may be infringing the patent licensed by the company that supplies Hemostase MPH to us. We have notified the supplier of Hemostase MPH about this potential infringement. We are not able to predict what actions the supplier will take. If the supplier does not take any action or if they are ultimately unsuccessful in their attempt to halt the infringement or in prohibiting other infringements of their patents or inappropriate uses of their company's proprietary technology, or should the validity of their licensed patents be successfully challenged, our revenues and profitability could be materially and adversely affected.

**We May Not Be Successful In Obtaining Necessary Clinical Results And Regulatory Approvals For Products And Services In Development, And Our New Products And Services May Not Achieve Market Acceptance.**

Our growth and profitability will depend, in part, upon our ability to complete development of and successfully introduce new products and services. We are uncertain whether we can develop new products and services to a

commercially acceptable form. We must also expend much time and money to obtain the required regulatory approvals. Although we have conducted preclinical studies on certain products under development which indicate that such products may be effective in a particular application, we cannot be certain that the results we obtain from expanded clinical studies will be consistent with earlier trial results or be sufficient for us to obtain any required regulatory approvals or clearances. We cannot give assurance that we will not experience difficulties that could delay or prevent us from successfully developing, introducing, and marketing new products. We also cannot give assurance that the regulatory agencies will clear or approve these or any new products on a timely basis, if ever, or that the new products will adequately meet the requirements of the applicable market or achieve market acceptance.

Our ability to complete the development of any of our products is subject to all of the risks associated with the commercialization of new products based on innovative technologies. Such risks include unanticipated technical or other problems, manufacturing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully develop or manufacture our products which are under development. If we do develop or manufacture these products, we may not do so on a timely basis. These products may not meet price or performance objectives, and may not prove to be as effective as competing products.

If we are unable to successfully complete the development of a product, application, or service, or if we determine for financial, technical, or other reasons not to complete development or obtain regulatory approval of any product, application, or service, particularly in instances when we have expended significant capital, this could materially and adversely affect our business, financial position, results of operations, and cash flows. Research and development efforts are time consuming and expensive and we cannot be sure that these efforts will lead to commercially successful products or services. Even the successful commercialization of a new service or product in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs. The introduction of new products or services, which could include new indications for our BioGlue products, new products based on our Protein Hydrogel Technology, such as BioFoam and BioDisc, CryoValve SG aortic human heart valve, and other products such as ProPatch, SynerGraft processed animal heart valves and vascular tissue, and products related to the cold storage and preservation of internal organs prior to transport, may require significant physician training and years of clinical evidence derived from follow-up studies on human implant recipients in order to gain acceptance in the medical community.

#### **Intense Competition May Affect Our Ability To Operate Profitably.**

We face competition from other companies engaged in the following lines of business:

- The processing of human tissue;
- The marketing of mechanical valves and synthetic and animal tissue for implantation; and
- The marketing of surgical adhesives, surgical sealants, and hemostatic agents.

Management believes that at least two domestic tissue banks offer preservation services for human heart valves and many companies offer processed porcine heart valves and mechanical heart valves, including St. Jude Medical, Inc., Medtronic, Inc., and Edwards Life Sciences.

Our BioGlue product competes with other surgical adhesives and surgical sealants, including Baxter International, Inc.'s Tisseel, FloSeal, and CoSeal, Ethicon, Inc.'s Evicel, Surgiflo, and Surgifoam, and Covidien, Ltd.'s Duraseal product. We are also aware that a few companies have surgical adhesive products under development. For example, Johnson & Johnson is under FDA review for a surgical adhesive for approval in vascular sealing that could compete with BioGlue in certain applications. Tenaxis, Inc. currently has approval for a surgical adhesive that could compete with BioGlue in certain applications. Other large medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our BioGlue product competes on the basis of its high tensile strength and ease of use.

Our Hemostase MPH product competes with thrombin products, including King Pharmaceuticals, Inc.'s Thrombin JMI, ZymoGenetics, Inc.'s Recothrom, and Omrix Biopharmaceuticals, Inc.'s Evithrom; and surgical hemostats, including Pfizer Inc.'s Gelfoam, C.R. Bard, Inc.'s Avitene, Baxter International, Inc.'s FloSeal, and Ethicon, Inc.'s Surgicel, Surgiflo, and Surgifoam products. In addition, Starch Medical, Inc. has a hemostatic product that has CE approval and that will compete in the future in Europe. We are also aware



that a few companies have surgical hemostat products under development. For example, Omrix Biopharmaceuticals Inc. is currently developing a hemostatic patch for control of surgical bleeding that could compete with Hemostase MPH in certain applications. Other medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our Hemostase MPH product competes on the basis of its safety profile and ease of use.

Many of our competitors have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. We have increased fees and prices on a number of our services and products since January 1, 2008. This increase may provide an opportunity for our competitors to gain market share. If we are unable to continue to increase prices as planned and retain or improve our market share, our ability to grow revenues and profits may be adversely affected.

We cannot give assurance that our products and services will be able to compete successfully. Any products that we develop that gain regulatory clearance or approval will have to compete for market acceptance and market share. In addition, our competitors may gain competitive advantages that may be difficult to overcome. If we fail to compete effectively, this could materially and adversely affect our business, financial position, results of operations, and cash flows.

**Our Products In Development May Never Generate Significant Revenues Or Income.**

Our plans for future growth are also partially dependent upon our products in development, including, without limitation:

- Our BioDisc spinal disc nucleus replacement,
- Our CryoValve SG aortic human heart valve,
- Our BioFoam for hemostasis and trauma repair,
- Our BioGlue Aesthetic<sup>®</sup>, for plastic surgery indications,
- Products related to the cold storage and preservation of internal organs prior to transport,
- Our SynerGraft processed animal heart valves and vascular tissue, and
- Our ProPatch for hernia repair.

These products are in various stages of testing and regulatory approval, and it is possible that some or all of them may not prove effective for the purposes that we have developed them, may not receive regulatory approval, or may not be accepted by the medical community. Should this be the case, these products may never generate significant revenues or profits.

**Investments In New Technologies And Acquisitions Of Products Or Distribution Rights May Not Be Successful.**

We may invest in new technology licenses, and acquire products or distribution rights that may not succeed in the marketplace. In such cases, we may be unable to recover our initial investment, which could include acquiring license or distribution rights, acquiring products, or purchasing initial inventory. Inability to recover our initial investment may adversely impact our profitability.

**If We Are Not Successful In Expanding Our Business Activities In International Markets, We Will Not Be Able To Pursue One Of Our Strategies For Increasing Our Revenues.**

Our international operations are subject to a number of risks which may vary from the risks we face in the U.S., including:

- Unexpected changes in regulatory requirements and tariffs;
- Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;

Adverse economic or political changes;  
More limited protection for intellectual property in some countries;  
Changes in currency exchange rates;  
Potential trade restrictions, exchange controls, and import and export licensing requirements; and  
Potentially adverse tax consequences of overlapping tax structures.

**Future Health Care Reimbursement Methods And Policies May Affect The Availability, Amount, And Timing Of Our Revenues.**

Even though we do not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for our preserved tissue and other services and products. Our preservation services with respect to the cardiac and vascular tissues we preserve may be particularly susceptible to third-party cost containment measures. For example, the initial cost of a preserved human heart valve generally exceeds the cost of a mechanical, synthetic, or animal-derived valve. We are unable to predict what changes will be made in the reimbursement methods and policies utilized by third-party health care payors or their effect on us.

If third-party health care payors, including Medicare, change their reimbursement methods and policies with respect to preserved tissues provided for implant by us and other services and products that we offer, this could have a material and adverse effect on us. Significant uncertainty exists as to the reimbursement status of newly approved health care products and services, and there can be no assurance that adequate third-party coverage will be available for us to maintain price levels sufficient to realize an appropriate return on our investment in developing new products.

If government-mandated health insurance is adopted, the demand for and prices obtained for our services and products could be negatively impacted because government-mandated health insurance could result in higher cost surgeries not being approved or could limit the level of reimbursement for new products, such as the CryoValve SG pulmonary human heart valve.

Government, hospitals, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA. In some cases, these entities refuse to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval. If government and other third-party payors do not provide adequate coverage and reimbursement levels for uses of our new products and services, market acceptance of these products would be adversely affected, which could negatively impact revenue growth and materially and adversely affect our business, financial position, results of operations, and cash flows.

**Rapid Technological Change Could Cause Our Services And Products To Become Obsolete.**

The technologies underlying our products and services are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop products or processes with significant advantages over the products and processes that we offer or are seeking to develop. Any such occurrence could materially and adversely affect our business, financial position, results of operations, and cash flows.

**Extensive Government Regulation May Adversely Affect Our Ability To Develop And Sell Products And Services.**

Government regulation in the U.S. and in Europe, the Middle East, and Africa, and other jurisdictions can determine the success of our and our competitors' efforts to market and develop services and products. Most of our products and services in development and those of our competitors, if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed. The process of obtaining premarket approvals from the FDA normally involves clinical trials as well as an extensive premarket approval application and often takes many years. In addition, the 510(k) notification process may also require clinical trials and take many years; for example the 510(k) clearance for the CryoValve SG pulmonary heart valve took four years. The process for approval from the FDA is expensive and can vary significantly based on the type, complexity, and novelty of the product. We cannot give any assurance that any

products developed by us or our competitors, independently or in collaboration with others, will receive the required approvals for manufacturing and marketing.

Delays in obtaining U.S. or foreign approvals could result in substantial additional cost and adversely affect our competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of our products. The FDA may withdraw product marketing approvals or clearances if we do not maintain compliance with regulatory standards or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which we have the exclusive right to commercialize patented products.

Delays or rejections may also be encountered by us during any stage of the regulatory approval process if clinical or other data fails to satisfactorily demonstrate compliance with, or if the product fails to meet, the regulatory agency's requirements for safety, efficacy, and quality. Those requirements may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials may also be delayed due to unanticipated side effects, inability to locate, recruit, and qualify sufficient numbers of patients, lack of funding, the inability to locate or recruit clinical investigators, the redesign of clinical trial programs, the inability to manufacture or acquire sufficient quantities of the particular product or any other components required for clinical trials, changes in development focus, and disclosure of trial results by competitors.

Even if we or one of our competitors are able to obtain regulatory approval for any products or services offered, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. The unapproved use of our products or our preserved tissues could adversely affect the reputation of our Company and our products or services. Products or services marketed pursuant to FDA or foreign oversight or approvals are subject to continuing regulation and periodic inspections. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. If we fail to comply with applicable FDA requirements, which may be ambiguous, we could face civil and criminal enforcement actions, warnings, citations, product recalls or detentions, and other penalties. This could materially and adversely affect our business, financial position, results of operations, and cash flows.

In addition, the National Organ Transplant Act of 1984 (NOTA), prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs. We cannot be certain that restrictive interpretations of NOTA will not be adopted in the future which will challenge one or more aspects of industry methods of charging for preservation services. Our laboratory operations and those of our competitors are subject to the U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations which govern the processing, transportation, and storage of human organs and tissue.

U.S. and foreign governments and regulatory agencies may adopt more restrictive laws or regulations in the future that could materially and adversely affect our business, financial position, results of operations, and cash flows.

#### **We Are Dependent On Our Key Personnel.**

Our business and future operating results depend in significant part upon the continued contributions of our key technical personnel and senior management, many of whom would be difficult to replace, including our CEO, Steven G. Anderson. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, technical, marketing, sales, and support personnel for our operations. Competition for such personnel is intense and we cannot ensure that we will be successful in attracting and retaining such personnel. We do not have key life insurance policies on any of our key personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain

skilled employees as needed, this could materially and adversely affect our ability to efficiently operate our business.

## **Risks Related To Our Common Stock**

### **Trading Prices For Our Securities Have Been, And May Continue To Be, Volatile.**

The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, including variations in operating results, regulatory actions such as the adverse FDA activity, product liability claims, announcement of technological innovations or new products by us or our competitors, governmental regulatory acts, developments with respect to patents or proprietary rights, general conditions in the medical device or service industries, actions taken by government regulators, changes in earnings estimates by securities analysts, or other events or factors, many of which are beyond our control. If our revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of our common stock would likely decline, perhaps substantially. Changes in the trading price of our common stock may bear no relation to our actual operational or financial results. If our share prices do not meet the requirements of the New York Stock Exchange, our shares may be delisted. The closing price of our common stock has ranged from a high of \$16.35 to a low of \$2.99 in the period from January 1, 2005 to September 30, 2008.

The market prices of the securities of biotechnology companies have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, companies that experienced volatility in the market price of their securities have often faced securities class-action litigation. Moreover, market prices for stocks of biotechnology and technology companies frequently reach levels that bear no relationship to the operating performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources, and materially and adversely affect our business, financial position, and results of operations.

### **Anti-Takeover Provisions May Discourage Or Make More Difficult An Attempt To Obtain Control Of CryoLife.**

Our Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of our company, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders, and prohibiting shareholders from taking action by written consent. In addition, we are subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of our common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995 and amended in 2005, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire our company on terms not approved by the Board of Directors and may deter hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices.

### **We Are Not Likely To Pay Common Stock Dividends In The Foreseeable Future, And We May Not Be Able To Pay Cash Dividends On Our Capital Stock Due To Legal or Contractual Restrictions And Lack Of Liquidity.**

We have not paid, and do not presently intend to pay, cash dividends on our common stock. In addition our credit agreement prohibits us from paying cash dividends, and under Florida law we may not be able to pay cash dividends on our capital stock. Under Florida law, no distribution may be paid on our capital stock, if after giving it effect:

We would not be able to pay our debts as they become due in the usual course of business; or  
Our total assets would be less than the sum of our total liabilities plus the amount that would be needed, if we were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of any preferred shareholders whose preferential rights are superior to those receiving the distribution.

The terms of any future financing arrangements that we may enter into may also restrict our ability to pay dividends.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

- (c) The following table provides information about purchases by the Company during the quarter ended September 30, 2008 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Common Stock

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/08 07/31/08	872	\$ 13.59		
08/01/08 08/31/08	8,224	14.99		
09/01/08 09/30/08	1,276	16.23		
Total	10,372	\$ 15.03		

The Company currently has no stock repurchase program, publicly announced or otherwise. The common shares shown were tendered to the Company in payment of the exercise price of outstanding options.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Item 5. Other information.**

None.

**Item 6. Exhibits.**

The exhibit index can be found below.

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 10-K for the year ended December 31, 2007.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed October 28, 2008.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

/s/ STEVEN G. ANDERSON  
STEVEN G. ANDERSON  
Chairman, President, and

Chief Executive Officer

(Principal Executive Officer)

October 30, 2008  
DATE

CRYOLIFE, INC.  
(Registrant)

/s/ D. ASHLEY LEE  
D. ASHLEY LEE  
Executive Vice President,

Chief Operating Officer, and

Chief Financial Officer

(Principal Financial Officer)